

Copenhagen University Hospital - Rigshospitalet
Center for Rheumatology and Spine Diseases

REGION

Report 2021

Copenhagen Center for Arthritis Research



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- in collaboration with the COPECARE team

The report is also available on our webpage, www.copecare.dk

Københavns Center for Artritforskning



COPECARE

Copenhagen Center for Arthritis Research

COPECARE: the Copenhagen arthritis research unit

Copenhagen Center for Arthritis Research (COPECARE) is a research unit within Center for Rheumatology and Spine Disease at Copenhagen University Hospital – Rigshospitalet, Denmark. Our work and ambition are centered around improving diagnostics, treatment, and quality of life for people with a rheumatic disease. Our research unit consists of highly skilled people within medical science, nursing, occupational therapy, physiotherapy, data management etc., each contributing to our establishment and success as an internationally renowned research unit.

Formally, COPECARE has existed for nearly 10 years, and we have had the pleasure to supervise many young, talented researchers. We have grown significantly in number and continue to grow – as does our network, the scale of our studies and the list of ideas for future projects and initiatives.

We share our knowledge through scientific publications, at congresses, through contact to the media and at different courses and events, which we regularly organize for both national and international healthcare professionals.

The multiple challenges related to rheumatic diseases are reflected in the numerous types of studies carried out at COPECARE. Most of our studies are investigator-initiated studies covering epidemiological, methodological and clinical studies in which radiography, ultrasound, MRI, soluble biomarkers, clinical quality data and patient reported outcomes are frequently incorporated. In several studies, the impact of treatment strategies and lifestyle changes are investigated, and some studies are carried out in collaboration with patients as patient research partners, contributing with unique and highly relevant insight, giving rise to new ideas and reflections and keeping us on our toes.



Abbreviations

ACR	American College of Rheumatology
ASAS	Assessment in Ankylosing Spondylitis
AxSpA	Axial spondyloarthritis
BME	Bone marrow edema
CBD	Cannabidiol
CBT-i	Cognitive Behavioral Therapy for insomnia
CCP	Cyclic Citrullinated Peptide
CDAI	Clinical Disease Activity Index
COPECARE	Copenhagen Center for Arthritis Research
CRP	C-Reactive Protein
CT	Computed Tomography
DANBIO	Danish Rheumatology Database
DAS28	Disease Activity Score 28
DECT	Dual-Energy Computed Tomography
DMARDs	Disease-Modifying Antirheumatic Drugs
HAQ	Health Assessment Questionnaire
HAQ-DI	Health Assessment Questionnaire-Disability Index
HbA1c	Hemoglobin A1c
IgM-RF	Immunoglobulin M rheuma factor
LDL	Low Density Lipoprotein
MR / MRI	Magnetic Resonance / Magnetic Resonance Imaging
MSK	Musculoskeletal
OMERACT	Outcome Measures in Rheumatology
PAD	Peptidylarginine Deiminase
PMR	Polymyalgia rheumatica
PROBE	Prospective Randomized Open Blinded End-point
PsA	Psoriatic Arthritis
PsAID	Psoriatic Arthritis Impact of Disease
PsO	Psoriasis
QoL	Quality of Life
RA	Rheumatoid Arthritis
RCT	Randomized Controlled Trial
SIJ	Sacroiliac joint
SJS	Sjögren's syndrome
SPARCC	Spondyloarthritis Research Consortium of Canada
THC	Tetrahydrocannabinol
TNF	Tumor Necrosis Factor
TNFi	Tumor Necrosis Factor inhibitors
US	Ultrasound
VAS	Visual Analogue Scale

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Year 2021 in brief

Similar to 2020, year 2021 was heavily influenced by the effects of the COVID-19 virus. Several precautions initiated in 2020 continued in the first part of 2021, including a partial shut-down during which public servants in non-critical positions were asked to work from home. Consequently, several research projects were further delayed, and activities such as meetings, congress attendance etc. were limited.

Despite sub-optimal conditions, we managed to stay productive. This was only possible due to great dedication and a notable team effort, leaving plenty of reasons to feel proud.

We were also very proud when two of our colleagues, physician Lene Terslev and nurse Bente Appel Esbensen were appointed professors in 2020, and extremely happy that we were finally able to properly celebrate their achievements in 2021.

During the year, we further had the pleasure to congratulate four of our PhD students as they successfully defended their PhD theses, covering the topics:

1. Magnetic resonance imaging of sacroiliac joints in the differential diagnosis to axial spondyloarthritis (physician Sengül Seven)
2. Association between imaging inflammation, pain and tenderness, disability, and health-related quality of life in relation to PsO and PsA (Sara Helena Kamp Felbo)
3. Axial spondyloarthritis: Clinical and magnetic resonance imaging of axial spondyloarthritis after dose changes in biological therapy (Marie Wetterslev)

4. Non-pharmacological treatment of sleep disturbances or sleep disorders in people with inflammatory arthritis (Kristine Marie Latocha)

We also welcomed 17 new colleagues, some of whom were familiar faces while others are new in the field of rheumatology.

The Scandinavian Congress of Rheumatology 2021 took place early September in Ålesund, Norway. Upon years with corona restrictions, it was great to finally be able to meet, network and celebrate Lene Terslev, who received the Scandinavian Rheumatology Research Foundation Award at the opening ceremony of the congress

Another face-to-face event took place in September 2021, when our EuroSpA team facilitated an imaging workshop for colleagues in the EuroSpA collaboration, focusing on MRI training and assessment of the sacroiliac joints

All in all, year 2021 offered several bright moments and reasons to be thankful and optimistic. We now look forward to a new year and send our best wishes to everyone who offered invaluable support such as funding and collaboration.



Mikkel Østergaard
Professor, Head of COPECARE

Organization

COPECARE is a research unit within Center for Rheumatology and Spine Diseases, Copenhagen University Hospital – Rigshospitalet. Our team consists of specialists within different professions such as medicine, nursing, physiotherapy, occupational therapy, data management and statistics.

Management group

Head of COPECARE, Professor, MD, PhD, DMSc Mikkel Østergaard
Professor, MD, PhD, DMSc Merete Lund Hetland
Professor, MD, PhD Lene Terslev
Professor, senior researcher, RN, MScIN, PhD Bente Appel Esbensen
Senior lecturer, consultant, MD, PhD, DMSc Ole Rintek Madsen
Consultant, MD, DMSc Henning Locht
Consultant, MD, PhD Bente Jensen
Registrar, MD, PhD René Panduro Poggenborg

Staff

Professor, MD, PhD, DMSc Mikkel Østergaard
Professor, MD, PhD, DMSc Merete Lund Hetland
Professor, consultant, MD, PhD Lene Terslev
Professor, senior researcher, RN, MScIN, PhD Bente Appel Esbensen
Senior lecturer, consultant, MD, PhD, DMSc Ole Rintek Madsen
Consultant, MD, DMSc, Henning Locht
Consultant, MD, PhD Bente Jensen
Registrar, MD, PhD René Panduro Poggenborg
Senior lecturer, consultant, MD, PhD, DMSc Bente Glintborg
Postdoc, MD, PhD Brigitte Michelsen
Postdoc, MD, PhD Louise Linde
Postdoc, MD, PhD Lykke Ørnbjerg
Postdoc, MD, PhD Mads Ammitzbøll Danielsen
Postdoc, MD, PhD Signe Kaas Møller-Bisgaard
Postdoc, MD, PhD MD Simon Krabbe
Postdoc, MD, PhD Susanne Juhl Pedersen
Postdoc, RN, MScIN, PhD Pernille Feveje Cromhout
Postdoc, MSc in human nutrition, PhD Kathrine Rugbjerg
Postdoc, OT, MScIH, PhD Tanja Thomsen
Datamanager, postdoc, MEng, PhD Stylianos Georgiadis
Datamanager, PhD Simon Horskjær Rasmussen
PhD student, MD Anna Enevold Fløistrup Hadsbjerg
PhD student, MD Ashish Mathew

ORGANIZATION

PhD student, MD Hafsah Nabi
PhD student, MD Kristian Zobbe
PhD student, MD Marie Wetterslev
PhD student, MD Nora Borislavova Vladimirova
PhD student, MD Sabine Sparre Dieperink
PhD student, MD Sara Helena Kamp Felbo
PhD student, MD Sara Nysom Christiansen
PhD student, MD Sengül Seven
PhD student, MD Stine Maya Dreier Carstensen
PhD student, RN, MSciH Kristine Marie Latocha
PhD student, RN, MSciH Luise Holberg Lindgren
Research assistant, RN, MSciH Charlotte Werdal Hansen
Research assistant, MD Tanja Gorlen
Research assistant, medical student Anne Emilie Secher
Research nurse Bonnie Britt Myhre
Research nurse, Master in Professional Communication (MPC) Lise Hejl Hyldstrup
Research nurse, Sannie Mahncke
Laboratory technician Debbie Nadelmann
Academic administrative officer, MSc in clinical nutrition Nina Schmidt
Academic administrative officer, MSc Christian Gøtze Hoeg
Academic administrative officer (EuroSpA), MSc in human physiology, Trine Egegaard
Secretary Maj-Brit Thyme Havlit
Secretary Linda Thomsen
Student assistant, Helena Victoria Grundtoft Elmo
Student assistant, Jeppe Aabye

Physicians and personnel associated with COPECARE

Chief physician, consultant, MD Annette Hansen
Consultant, MD, PhD Henrik Skjødt
Consultant, MD, PhD Lars Juul
Consultant, MD, PhD Mette Bjørndal Axelsen
Consultant, MD, PhD Mogens Pfeiffer Jensen
Consultant, MD, PhD Uffe Møller Døhn
Consultant, MD Anne Rødgaard
Consultant, MD Dorte Vendelbo Jensen
Consultant, MD Gorm Thamsborg
Consultant, MD Ole Slot
Consultant, MD Torsten Møller
Consultant, MD Viktoria Fana
Senior registrar, MD Toke Laursen
PhD student, senior registrar, MD Pernille Hurup Duhn
Academic administrative officer (DANBIO) Klaus Westenbæk

Ongoing projects

Our research projects cover both local, national and international studies including cohort studies, clinical trials, registry studies, imaging studies, biomarker studies, and meta-analyses. Most of these are investigator-initiated studies, some embedded in PhD projects.

PhD projects

Optimizing the use of MRI for classification of axial spondyloarthritis

MRI has been used for classification of axial spondyloarthritis (axSpA) for ≥ 10 years as part of the ASAS classification criteria. However, there is still a need for optimizing the use of MRI in axSpA since several conditions can resemble axSpA, the readings of MRIs can be questionable and other inflammatory diseases such as psoriatic arthritis (PsA) and rheumatoid arthritis (RA) can also affect the axial skeleton but, possibly, in different patterns.

This PhD study aims to investigate and optimize the use of MRI for classification of axSpA by increasing the knowledge of the appearance of differential diagnoses and potential pitfalls in image interpretation. The PhD study is divided into five sub-studies; studies 1 and 2 are part of a European collaboration and will investigate the agreement between local and central readings of MRIs and an MRI equivalent to the radiographic changes in axSpA, respectively. Study 3 will investigate the axial MRI findings in patients with PsA and RA and their response to treatment. Study 4 investigates the long-term findings in post-partum women, and study 5 investigates the baseline characteristics for patients who change diagnosis from non-radiographic axSpA to radiographic axSpA after 5 years. This PhD project will contribute to an improved way of using MRI in clinical practice and research.

PhD student: Anna Hadsbjerg

Internal supervisors: Mikkel Østergaard (principal supervisor), Lykke Midtbøll Ørnbjerg, Susanne Juhl Pedersen, Simon Krabbe

External supervisor: Professor, MD, PhD, Consultant Radiologist Mikael Ploug Boesen, Head of Musculoskeletal imaging, Department of Radiology, Copenhagen University Hospital, Bispebjerg and Frederiksberg,

Training and assessment of musculoskeletal skills

In this PhD project, Stine Maya Dreier Carstensen examines the effect of theoretical knowledge on practical performance in musculoskeletal ultrasound (MSUS), using a novel developed e-learning ultrasound platform. Moreover, she aims to collect validity evidence for using and interpreting two assessment tools, one assessing MSUS skills (Objective Structures Assessment of Ultrasound skills) and one assessing interventional MSUS skills (Interventional Ultrasound Skills Evaluation).

PhD student: Stine Maya Dreier Carstensen

Internal supervisors: Lene Terslev (principal supervisor), Mikkel Østergaard, Morgens Phiffer-Jensen

External supervisors: Lars Konge, Professor, Copenhagen Academy for Medical Education and Simulation (CAMES), Center for Human Resources and Education, The Capital Region of Denmark, Søren Andreas Just, Associate Professor, Consultant in Rheumatology, PhD, Section of Rheumatology, Department of Medicine, Svendborg Hospital - Odense University Hospital, Svendborg,

ONGOING RESEARCH PROJECTS**A self-management intervention targeted patients with newly diagnosed inflammatory arthritis**

Despite successful medical treatment, patients with inflammatory arthritis (IA) may still experience reduced quality of life, depression, anxiety, changes in family roles, work life, and social relationships. Several studies have shown that particularly newly diagnosed patients need support to learn to live with the disease.

The overall aim of this PhD study is to develop, test, and evaluate a self-management intervention for patients newly diagnosed with IA. The study includes five sub-studies: 1) development of an evidence and theory-based intervention aiming to increase self-management in newly diagnosed patients with IA, 2) a feasibility study for evaluation of the process, instruments, and methods used, 3) a qualitative evaluation of the intervention and intervention delivery based on observations of health professionals delivering the intervention and interviews with health professionals and patients, 4) a qualitative study identifying patients' self-management skills at baseline and at the end of feasibility through template-based interviews with patients, and 5) a cross-sectional study in which illness perception is analyzed in newly diagnosed patients.

PhD student: Luise Holberg Lindgren

Internal supervisors: Bente Appel Esbensen, Merete Hetland og Tanja Thomsen

Long-term studies in patients with inflammatory rheumatic diseases: investigating the consequences of single or multiple biosimilar switches on treatment effectiveness, drug safety, patient-reported outcomes and health-economy

Denmark has extensive use of the biological (bDMARD) biosimilar products in routine care. Based on national guidelines, mandatory switch procedures from originator to biosimilar bDMARDs and between biosimilars are implemented routinely to save medication costs. Thus, several thousand patients with inflammatory rheumatic diseases are switched to new biosimilars each year. Currently, the evidence supporting this practice is limited. A biosimilar drug is a highly similar, but not identical, version of the originator biological. Due to their complexity, biosimilars are susceptible to structural alterations that could potentially affect both efficacy and safety. Data from the few existing trials cannot be generalized to other originator-biosimilar combinations.

In this PhD project, Hafsa Nabi investigates the consequences of mandatory single or multiple biosimilar switches in routine care focusing on treatment effectiveness, drug safety, patient-reported outcomes and health-economy, mainly related to adalimumab and infliximab. The project is based on prospectively collected data from the Danish nationwide rheumatological clinical registry, DANBIO, linked with relevant national registries for information regarding comorbidities, vital status etc. This provides a unique opportunity for high-quality post-marketing pharmacovigilance studies of biological drugs used in the treatment of patients with inflammatory arthritis.

PhD student: Hafsa Nabi

Internal supervisor: Bente Grintborg (principal supervisor), Merete Lund Hetland

Invasive bacterial infections in persons with rheumatoid arthritis

Blood poisoning caused by staphylococcus is a common infection which is associated with high mortality and risk of complications such as infections of joints and infective endocarditis. Rheumatoid arthritis and the treatment of rheumatoid arthritis increases risk of infections, and results from minor studies indicate that infections are more frequent and severe for these patients compared to the overall population. However, existing knowledge on this topic is limited.

In her PhD project, Sabine Sparre Dieperink investigates incidence, risk factors, morbidity and mortality

due to blood poisoning with staphylococcus in patients with rheumatoid arthritis. This is done in a national cohort study using data from 1996-2017, obtained from the staphylococcus registry and the clinical rheumatological database, DANBIO. These data are merged with data from other national registries, providing information on hospital contact frequencies, prescriptions and socioeconomic factors.

Overall, this project covers a comprehensive exploration, including identification of possible risk factors such as treatment with conventional and biological DMARDs and glucocorticoids, presence of artificial joints as well as joint damages due to rheumatoid arthritis.

PhD student: Sabine Sparre Dieperink

Internal supervisors: Merete Lund Hetland (principal supervisor), Bente Glinborg

Extent, pattern, and responsiveness of MRI-assessed axial disease in patients with axial spondyloarthritis, psoriatic arthritis and inflammatory bowel disease

Psoriatic arthritis (PsA), inflammatory bowel disease-related spondyloarthritis (IBD-SpA) and axial SpA are parts of the spondyloarthritis (SpA) group of disorders, which all involve inflammation in sacroiliac joints and spine, frequently treated by biologics.

MRI is now established as the optimal method for detecting early SpA and for monitoring disease activity and treatment response. To date little research has been done specifically on axial PsA and IBD-SpA.

Since conventional radiography has found considerable differences in the pattern of structural changes across the SpA spectrum and because certain therapies work differently in peripheral PsA, axSpA and IBD, it is very important to clarify the specific axial findings in those patients and to investigate to which extent they respond to different types of therapies.

On this background the present PhD study aims to determine the MRI characteristics and their responsiveness in patients with axSpA, PsA and IBD, scheduled for biological treatment initiation.

PhD student: Nora Borislavova Vladimirova

Internal supervisors: Mikkel Østergaard (principal supervisor), Lykke Midtbøll Ørnbjerg, Merete Lund Hetland, Susanne Juhl Pedersen

External supervisors: Johan Burisch, registrar, PhD, Gastrounit, Medical division, Hvidovre Hospital

Risk of mortality and co-morbidities as well as impact of weight loss in gout patients: a clinical and epidemiological research project

This PhD project aims to expand our basic knowledge of gouty arthritis incidence, prevalence and mortality as well as co-morbidities such as cancer and overweight. This is explored in a series of epidemiology studies, which are carried out in collaboration with Oxford University. The studies will be based on Danish and British national registries. The effect of weight loss on serum urate will be tested in a placebo controlled clinical trial of overweight patients with gout.

PhD student: Kristian Zøbbe

Supervisors: Lene Dreyer (principal supervisor), Professor, Aalborg University Hospital, Jens Skøt, MD, Søborg, Copenhagen, Lars Erik Kristensen, CSO, PhD, The Parker Institute

Enthesitis in psoriatic arthritis – utility of magnetic resonance imaging

Enthesitis is a common clinical feature of psoriatic arthritis, which plays a crucial role in its pathogenesis. There is scarcity of clinical and MRI data related to enthesitis in psoriatic arthritis.

This PhD project aims at understanding the overall burden of clinical enthesitis in longitudinal cohorts, and to enable better utility of MRI in diagnosis and outcome measurement of enthesitis in psoriatic

ONGOING RESEARCH PROJECTS

arthritis. The imaging part of the project focus on developing a consensus-based MRI scoring system for enthesitis in psoriatic arthritis and spondyloarthritis, informed by a systematic literature review, in collaboration with the OMERACT MRI in arthritis working group. This MRI scoring system will undergo validation in psoriatic arthritis patients with enthesitis, and an atlas with representative images of MRI pathologies in enthesitis will be developed for use by prospective scorers. The clinical part of the project aims to study the prevalence and distribution of enthesitis, and effectiveness of disease modifying anti-rheumatic drugs in patients with psoriatic arthritis from three well-recognized, real-life, longitudinal cohorts, including the Toronto psoriatic arthritis cohort, the DANBIO and the EuroSpA collaboration.

PhD student: Ashish Jacob Mathew

Internal supervisor: Mikkel Østergaard (principal supervisor)

External supervisors: Debashish Danda, Professor, DMSc, FRCP, Christian Medical College, Vellore, India, Vinod Chandran, Professor, DMSc, PhD, University of Toronto, Toronto, Canada, Philip Conaghan, Professor, FRACP, PhD, FRCP, University of Leeds, Leeds, UK

Non-pharmacological treatment of sleep disturbances and sleep disorders in people with inflammatory arthritis

More than 50% of all patients with inflammatory arthritis have sleep disturbances or insomnia, which can affect pain, fatigue, quality of life and risk of comorbidities. Initial treatment of insomnia is often based on pharmacological drugs, however, cognitive behavioral therapy for insomnia (CBT-I) appears more effective in some patient populations.

Kristine Marie Latocha's PhD project aims to investigate non-pharmacological treatment of sleep disturbances and sleep disorders in people with inflammatory arthritis. An evidence synthesis is conducted to investigate the evidence of non-pharmacological interventions targeting sleep disturbances or disorders in this group of patients, an RCT is conducted to investigate the effect of CBT-I on sleep- and arthritis-related parameters in patients with rheumatoid arthritis, and a qualitative study is conducted to explore experiences of CBT-I in patients with rheumatoid arthritis.

Altogether, this project contributes to increased attention on identifying sleep disturbances and sleep disorders in arthritis, increased focus on relevant evidence-based treatment, and, consequently, also on the important management of arthritis-related symptoms and burdens.

PhD student: Kristine Marie Latocha

Internal supervisors: Bente Appel Esbensen (principal supervisor), Mikkel Østergaard

External supervisors: Poul Jørgen Jennum, Professor, consultant, DMSc, Danish Center for Sleep Medicine, Department of Neurophysiology, Copenhagen University Hospital – Rigshospitalet, Glostrup, Robin Christensen, Professor, PhD, the Parker Institute, Katrine Bjerre Løppenthin, nurse, MScH., Department of Oncology, Copenhagen University Hospital – Rigshospitalet

Characterization and monitoring of different phenotypes of peripheral psoriatic arthritis by modern imaging – and their impact on physical and psychological aspects of patients' lives

This PhD project investigates the use of sensitive imaging methods (US and MRI) accompanied by patient reported outcome measures for diagnosing and monitoring peripheral manifestations of psoriatic arthritis. It is based on a series of sub-studies; 1) a methodological study examining elementary US components in dactylitis and enthesitis, 2) a population based multicentre cohort study investigating the prevalence of musculoskeletal pain and psoriatic arthritis among patients with psoriasis, evaluated by questionnaires, clinical, US and biochemical examination, and how these findings correlate and change during therapy and 3) a longitudinal follow-up study of patients with psoriasis, initiating biological therapy for their skin disease at baseline, assessing effect of treatment on potential clinical

and/or subclinical inflammatory changes in joints and entheses by US and patient reported outcomes. The project is expected to improve methods to establish diagnosis and monitor disease activity in patients with psoriatic arthritis.

PhD student: Sara Helena Kamp Felbo

Internal supervisors: Mikkel Østergaard (principal supervisor), Lene Terslev, Inge Juul Sørensen

Dose adjustment of biological treatment in patients with spondyloarthritis

The aim of the main study in Marie Wetterslev's PhD project is to treat patients with spondyloarthritis with the lowest possible effective dose of biological therapy and to determine the overall proportion of patients that can have their biological therapy reduced. The study is designed as an open label longitudinal quality control study, in which patients with spondyloarthritis in remission have their dose of biological treatment reduced according to a predefined treatment algorithm, ensuring optimal dose. Patient flare is assessed with patient-reported outcomes, clinical measures and imaging measures. In addition, blood samples are collected to assess the predictive value of soluble flare biomarkers in patients with spondyloarthritis.

PhD student: Marie Wetterslev

Internal supervisors: Mikkel Østergaard (principal supervisor), Merete Lund Hetland, Inge Juul Sørensen, Cecilie Cornelia Heegaard Brahe, Susanne Juhl Pedersen

Ultrasonography for optimized diagnosis and management of gout

Ultrasonography (US) is commonly used in inflammatory arthropathies, and in patients with gout US can visualize urate depositions. However, the utility of US in gout has only been examined in few studies. This PhD study aims to further develop US for optimized diagnosis and management of gout. The study is divided into four sub-studies. In the first sub-study, the utility of US as a diagnostic tool in gout is explored, and in the second sub-study, US is used to monitor gout patients. In the third sub-study, the aim is to develop an expert consensus-based semi-quantitative scoring system for the US gout lesions indicative of urate depositions. In the fourth sub-study, DECT is used to scan gout patients and the specific properties and locations of the color-coded DECT lesions in gout patients are described.

PhD student: Sara Nysom Christiansen

Internal supervisors: Lene Terslev, Mikkel Østergaard (principal supervisor), Ole Slot

Other research projects

A nationwide COVID-19 questionnaire survey in patients with rheumatic disorders

The COVID-19 pandemic has had a huge impact on patients with inflammatory rheumatic diseases – not only do they risk having COVID-19, but fear of the infection may affect behavior and access to health care resources in various manners. With this nationwide questionnaire survey, we explore if and how the pandemic changes rheumatic disease control – e.g. patient reported outcomes, access to treatment, adherence to medication, and self-management (isolation strategies, anxiety, concerns, work-situation etc). The survey is repeated three times with 6-8 months' intervals in parallel to the implementation of the DANBIO-from-home- solution which is an opportunity for patients monitored in DANBIO to report outcomes and answer questionnaires from home.

Bente Glinthorg, Merete Lund Hetland, Dorte Vendelbo Jensen, Mikkel Østergaard, Lene Terslev, Mogens Pfeiffer Jensen

ONGOING RESEARCH PROJECTS**COVID-19 infection in rheumatic patients in immunosuppressive treatment**

Patients with rheumatic disorders treated with biological drugs are four times more likely to develop severe infections compared to the average population. The COVID-19 virus has caused concern for this group of patients, who may be more severely affected by a COVID-19 infection.

In a national cohort study using data from DANBIO, absolute and relative risk of COVID-19 infection, hospitalization, morbidity and mortality among patients with a rheumatic disease treated with immunosuppressive pharmaceuticals is compared to the average population. Impact of diagnosis and medical treatment on these COVID-19 outcomes is also explored as well as development of COVID-19 immunity among infected patients. All patients fill out web-based questionnaires, which are coupled with clinical data from DANBIO, data from other relevant registries such as LPR and LSR and results from COVID-19 antibody testing.

Bente Glintborg, Dorte Vendelbo Jensen, Mogens Pfeiffer Jensen, Lene Terslev, Mikkel Østergaard, Merete Lund Hetland

Targeted self-management in people with inflammatory arthritis (TASEMA)

This comprehensive research programme consists of three work-packages and multiple sub-studies, aiming to improve self-management and thereby lives of people with inflammatory arthritis. The TASEMA programme includes the development of self-management interventions, feasibility-studies to evaluate and adjust the interventions, and two RCTs to test the interventions in larger populations: One study focusing on newly diagnosed people and the other on people with severe disease burden despite well-regulated medical treatment. The TASEMA programme further aims to investigate psychosocial health in inflammatory arthritis. This is done in a cross-sectional study focusing on prevalence of anxiety and depression and their association with QoL. Additionally, a qualitative study using focus group interviews will capture patients' own perspectives of psychosocial health incl. their suggestions for support in a self-management context. The TASEMA programme is carried out in collaboration with Danish Hospital for Rheumatic Diseases, Sønderborg, Department of Rheumatology, Aarhus University Hospital, Centre for Clinical Research and Prevention, Bispebjerg and Frederiksberg Hospital and The University Hospitals Centre for Health Research, Copenhagen University Hospital – Rigshospitalet.

Bente Appel Esbensen, Mikkel Østergaard, Pernille Feveje Cromhout, Luise Holberg Lindgren, Merete Lund Hetland, Bente Glintborg

A phase 4, multicenter, single-arm, open-label study to evaluate the impact of apremilast (CC-10004) on MRI outcomes in subjects with psoriatic arthritis (MOSAIC)

This project is a non-blinded, phase IV, international, multicenter, single group study, which aims to include 120 patients with psoriatic arthritis. The aim of the study is to measure the effect of apremilast based on MR-imaging. The treatment period is 48 weeks and is followed by 4 weeks follow-up.

Mikkel Østergaard, Marie Wetterslev, Pernille Hurup Duhn

An adaptive phase 2 randomized double-blind, placebo-controlled multi-center study to evaluate the safety and efficacy of multiple LOU064 doses in patients with moderate to severe Sjögren's Syndrome (LOUISse)

Sjögren's syndrome (SJS) is a chronic autoimmune disease which mainly affects glands producing saliva and tears. Typical symptoms are dryness of mouth and eyes, fatigue, dry skin, and muscle and joint pain. LOU064 is a relatively small molecule, which binds to B-cells, and is currently being tested as a treatment

of SJS. In this double-blinded, placebo-controlled trial we investigate if LOU064 can reduce disease activity in patients with SJS and thereby reduce clinical symptoms.

Lene Terslev, Viktoria Fana

The efficacy and safety of using cannabis derivatives cannabidiol (CBD) and tetrahydrocannabinol (THC) treatment in patients with inflammatory arthritis. A randomized, double blinded, placebo controlled trial (CAN-ART)

This investigator-initiated multicenter study aims to explore the medical effect of pharmaceutical cannabis compared to placebo in patients with rheumatoid arthritis and axial spondyloarthritis. In a placebo-controlled, double-blinded setting, patients are initially treated with either CBD or placebo. After 12 weeks, patients with insufficient effect of this initial treatment are switched to either CBD or THC (non-blinded). The main goal of the study is to investigate if treatment with CBD results in a clinically relevant pain reduction compared to placebo.

Mikkel Østergaard, Merete Lund Hetland, Sabine Sparre Dieperink

Personalized medicine in RA by combining genomics, biomarkers, clinical and patient-derived data from the Nordic countries (NORA)

In this Nordic collaboration, existing biological material from clinical studies in Denmark (including material from the Danish Rheumatologic Biobank, DRB), Norway and Sweden is used to identify models to predict prognosis and treatment effect on an individual level through a combination of clinical information and biomarkers. New prospective studies are also initiated and include collection of patient-centered data and validation of findings from historical cohorts.

Bente Glintborg, Merete Lund Hetland, Bente Appel Esbensen

Patients with rheumatoid arthritis and synovitis treated with ultrasound guided intraarticular or intramuscular glucocorticoid injection – a randomised, double-blind, controlled study (Panguian)

Panguian is a double-blinded randomized intervention study designed to investigate if an US-guided intraarticular glucocorticoid injection is superior to an intramuscular glucocorticoid injection in patients with rheumatoid arthritis. The study involves 100 patients with rheumatoid arthritis and treatment requiring synovitis. Injections are made at baseline and the effect is evaluated at baseline, week 4 and 12 by means of US-grading of synovitis changes, clinical evaluation, local joint pain, DAS28/44, CDAI, HAQ, VAS global pain and VAS fatigue.

Mads Ammitzbøll Danielsen, Merete Lund Hetland, Mikkel Østergaard, Lene Terslev

Prevalence, pattern and disease course of arthritis and enthesitis in patients with psoriasis, and effect of apremilast in subclinical US-defined psoriatic arthritis – a population-based study applying clinical, ultrasonic, MRI and patient-reported outcomes (DANPAPP)

DANPAPP is an investigator-initiated study within the field of psoriasis and psoriatic arthritis. It consists of three sub-studies. The first sub-study is centered around a national, e-based questionnaire, exploring prevalence of skin and joint discomforts, level of physical function, quality of life, contact with the health care system etc. Participants are subsequently invited to a medical examination looking for signs of psoriatic arthritis (sub-study II). Investigations are based on US-examinations of joints and entheses combined with patient reported parameters such as quality of life, level of physical functioning, fatigue and sleep quality. Sub-study III is a 12-month follow-up on patients who (based on US-examinations) had signs of inflammation. The aim of the study is to compare the prevalence of clinical and US-

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evaluated signs of inflammation in joints and entheses in patients with psoriasis with and without musculoskeletal pain, and patients with psoriatic arthritis. Furthermore, the relevance of such findings compared to patient reported parameters is explored. Based on this, a new questionnaire, PsAID, is evaluated. Finally, the effect of treatment with apremilast on US-findings and patient reported effect parameters are evaluated in patients with US-verified inflammation in joints and entheses.

Sara Helena Kamp Felbo, Lene Terslev, Mikkel Østergaard

Measurement uncertainties of clinical effect parameters (JUDAS)

Based on data from other studies, measurement uncertainties of clinical effect parameters used in rheumatology are explored.

Ole Rintek Madsen

Treat-to-target (T2T) with secukinumab in axial spondyloarthritis. Identification of MRI and biochemical biomarkers for disease activity, treatment response and structural damage progression (TRACE)

In this study disease activity and MR-evaluated inflammation are investigated and compared in patients with spondyloarthritis. The patients are instructed to follow a specific treatment strategy – initially with secukinumab (biological treatment). Depending on the achieved effect, treatment dose may be upregulated. If no effect is achieved despite adjustment of dose, patients are switched to treatment with TNF-inhibitors.

Sengül Seven, Nora Vladimirova, Mikkel Østergaard, Susanne Juhl Pedersen

Validation of the Danish versions of “the Bristol Rheumatoid Arthritis Fatigue Multi-Dimensional Questionnaire” (BRAf MDQ) and “the Bristol Rheumatoid Arthritis Fatigue Numerical Rating Scales” (BRAf NRS V2)

Many patients with rheumatoid arthritis complain about fatigue, however, the degree of fatigue can be difficult to measure. Good questionnaires are necessary to investigate if new initiatives can reduce fatigue. Two fairly new questionnaires about fatigue have been translated from English to Danish. The questionnaires, which consist of a full version and a shortened version, evaluate different types of fatigue, the level of fatigue, the impact on everyday life, and how fatigue is being handled. The aim of the study is to validate the Danish translated questionnaires to justify their use in future Danish studies. The project is carried out in collaboration with rheumatological departments in Sønderborg and Aarhus.

Bente Appel Esbensen

A randomized, partially-blinded, active-controlled multicenter study of secukinumab to demonstrate reduction of radiographic progression versus GP2017 (adalimumab biosimilar) at 104 weeks and to assess the long term safety, tolerability and efficacy up to 2 years in patients with active ankylosing spondylitis (SURPASS)

In this randomized, partly blinded multicenter study, the effect of secukinumab vs. GP2017 is compared in patients with spondyloarthritis with indication for biological treatment. Primary effect parameters are radiographic progression in pelvis and spine during a period of 104 weeks. 837 patients are expected to be included.

Sengül Seven, Mikkel Østergaard

Is the biomarker 14-3-3 η an independent predictor of rheumatoid arthritis development in patients with early undifferentiated arthritis (TUDAR 14-3-3 η)

Rheumatoid arthritis can cause damage to joints, reduced quality of life, and disabilities. Early treatment is crucial to ensure improvements in the disease state, and for this reason it is relevant to know how to predict development of rheumatoid arthritis. The protein 14-3-3 η , is a promising biomarker for the development of rheumatoid arthritis. Based on data from 117 patients with undifferentiated arthritis and 21 healthy control subjects the prognostic value of 14-3-3 η is explored.

Nina Schmidt, Mikkel Østergaard

EuroSpA

EuroSpA is a comprehensive research network consisting of experts and registries from 15 European countries. Numerous research projects within "real world" treatment of patients with spondyloarthritis and psoriatic arthritis erupt from this collaboration, which is led by an international scientific committee with participants from each participating country. Coordination is managed by the EuroSpA Coordinating Center, located at our department in Glostrup.

Merete Lund Hetland, Mikkel Østergaard, Lise Hejl Hyldstrup, Lykke Midtbøll Ørnbjerg, Brigitte Michelsen, Louise Linde, Stylianos Georgiadis, Simon Horskjær Rasmussen, Kathrine Rugbjerg, Simon Krabbe, Bente Glintborg

Side effects of original vs biosimilar etanercept

In connection with the marketing of biosimilar drugs, patients in Denmark were switched from the original drugs to the less expensive biosimilar drugs. This first happened with infliximab and in 2017 with etanercept. The purpose with this observational epidemiological study is to investigate potential differences in side effects between original etanercept compared to biosimilar etanercept, focusing mainly on side effects related to liver and bile ducts.

Bente Glintborg, Merete Lund Hetland

Factors of importance to treatment response and prognosis in rheumatoid arthritis

The aim of this study is to explore the importance of various clinical factors with respect to treatment effect of biological drugs and conventional synthetical drugs in rheumatoid arthritis. A special interest is given to the importance of IgM-RF-status, anti-CCP status, presence of erosive changes on X-ray of hands and feet at the time of treatment start. The study is an epidemiological study based on data from DANBIO and national registries.

Bente Glintborg, Merete Lund Hetland

Rheumatism and fatigue - rheumatoid arthritis, psoriatic arthritis and spondyloarthritis

This regional questionnaire survey is initiated to explore prevalence and consequences of fatigue in patients with rheumatoid arthritis, psoriatic arthritis and spondyloarthritis. Tests for correlations with performance and productivity at work, health related quality of life, pain, sleep difficulties, depression, and physical function are conducted. Patients are recruited from our department at Frederiksberg and Glostrup, and a total number of 500 patients is expected.

Bente Appel Esbensen

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Prediction model for severe infections in patients with rheumatoid arthritis, spondyloarthritis, and psoriatic arthritis, treated with biological drugs

Based on data from DANBIO, a prediction model is being developed to estimate the risk of severe infections on an individual level in patients with rheumatoid arthritis, spondyloarthritis and psoriatic arthritis, treated with biosimilar drugs.

Simon Krabbe, Kathrine Grøn, Bente Glintborg, Mikkel Østergaard, Merete Lund Hetland

Inflammation in arthritis assessed by ultrasound and peptidylarginine deiminase 2 and 4 – a pilot study

This research project is carried out in collaboration with Institute for Inflammatory Research. It aims to determine if the level of neurotransmitter (PAD2 and PAD4) varies in synovial fluid in patients with rheumatoid arthritis and spondyloarthritis with clinical signs of disease activity, and if these levels correlate with disease activity evaluated by US and clinical evaluation (DAS28).

Lene Terslev, Claus H Nielsen, Dres Damgaard, Uffe Møller Døhn, Viktoria Fana, Mads Ammitzbøll, Merete Lund Hetland, Mikkel Østergaard

Biosimilar drugs in rheumatology

Effects and adverse events during treatment with biosimilar drugs among Danish rheumatic patients are investigated in this study which also includes immunological and health economic aspects. The study data consists of data from DANBIO and other national registries and from analyzed blood samples provided by the Danish Rheumatologic Biobank.

Bente Glintborg, Hafsa Nabi, Merete Lund Hetland

A Nordic rheumatology register pilot to facilitate collaborative studies based on linkages of clinical data with national health

The Nordic Registries collaboration aims to investigate barriers towards epidemiological research across Nordic countries. This is done in a series of studies, which also intend to uncover possible solutions.

Merete Lund Hetland, Bente Glintborg, Lene Dreyer

Gender-related differences in disease management and preferences for support services in patients with arthritis (FAM-CAPICIA)

This national and online-based questionnaire survey aims to uncover potential gender dependent differences with respect to experiences, management and accept of inflammatory arthritis as well as potential differences in offers related to support and activities.

Bente Appel Esbensen

Multifactorial intervention to prevent cardiovascular disease in patients with early rheumatoid arthritis: a multicentre, prospective, randomised, open, blinded endpoint trial (ERACORI)

Rheumatoid arthritis is associated with several comorbidities and is an independent risk factor for ischemic heart disease. The focus of this study is the prevention of cardiovascular disease in patients with early rheumatoid arthritis by means of national guidelines for hypertension, elevated LDL cholesterol, microalbuminuria and HbA1c. The study is designed as a prospective, randomized study

with blinded endpoints (PROBE-design) and may reveal if an intensive treatment strategy can reduce the prevalence of cardiovascular heart disease in patients with rheumatoid arthritis.

Henning Locht, Bjarke Askaa, René Panduro Poggenborg, Annemarie Lyng Svensson

Physical activity - a survey among patients and health professionals in Sweden, Ireland, Denmark and Belgium

This questionnaire survey explores patients' and health care professionals' view on physical activity and the measurement of physical activity including the use of instruments such as accelerometer and pedometer. The study concerns patients with rheumatoid arthritis, psoriatic arthritis and spondyloarthritis and is carried out in collaboration with rheumatological departments in Sweden, Ireland, Denmark and Belgium.

Bente Appel Esbensen

A multicenter, randomized, open-label, blinded-assessor, phase 4 study in patients with early rheumatoid arthritis to compare active conventional therapy versus three biologic treatments, and two de-escalation strategies in patients who respond to treatment (NORD-STAR)

This Nordic investigator-initiated study of patients with newly diagnosed rheumatoid arthritis aims to investigate the optimal treatment and medical downsizing within this patient category. A total of four different treatment strategies and two downsizing strategies are compared.

Merete Lund Hetland (national PI), Simon Krabbe, Kathrine Lederballe Grøn, Sara Nysom Christiansen, Lykke Midtbøll Ørnbjerg, Sabine Sparre Dieperink, Mikkel Østergaard

Predictive value of visual and quantitative FDG-PET/CT scores for final diagnosis of polymyalgia rheumatica (PMR) and effects of prior steroid treatment.

Polymyalgia rheumatica (PMR) is a rheumatic syndrome characterized by muscle aching and stiffness, especially in the pectoral girdle, often accompanied by fever and fatigue. PMR can be diagnostically challenging, as symptoms may be diffuse and non-specific mimicking many other diseases and an unambiguous diagnostic test is lacking. Therefore, the diagnosis of PMR is still mainly clinical although supported by clinical biochemistry and various imaging modalities. FDG-PET is increasingly used in the diagnostic and differential diagnostic workup, often showing characteristic periarticular FDG-uptake. The aim of the study is to evaluate the performance of FDG-PET in diagnosing PMR including the effects of prior glucocorticoid treatment on FDG-PET sensitivity. Methods: A retrospective study including all patients aged ≥ 40 years consecutively referred to an FDG-PET/CT scan for any indication by the Department of Rheumatology; Gentofte Hospital, from 2016 to 2019. Clinical and laboratory data are obtained from the electronic patient records. The final diagnosis given 6 months after the FDG-PET/CT-scan is considered the reference standard for PMR.

Louise S Brith, Rikke Broholm, Martin Krakauer, Ole Rintek Madsen, Annette Hansen, Dorte Vendelbo Jensen.

Is ultrasound remission a real remission? Does ultrasound permit to achieve and maintain the remission in rheumatoid arthritis patients more efficiently than clinical scores? (REVECHO)

The REVECHO study is a European multicenter study, investigating if duration of remission can be prolonged by combining clinical examinations with US scans in connection with the regular control visits in the outpatient clinic. A total of 450 patients, who have been in clinical remission for at least three

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months, are randomized to be monitored by either 1) clinical practice with addition of US scans, 2) using DAS28 or 3) clinical practice alone. In arm 1, treatment is adjusted based on US evaluations, in arm 2 if DAS28 > 2.6, and in arm 3 if clinical signs of disease activity appear. The patients are followed for 18 months with US and clinical examination every third month. Primary effect parameters are duration of remission without flare in arm 1 compared to arm 2 and 3.

Lene Terslev, Uffe Møller Døhn

Lyme arthritis – a rare diagnose in Denmark

Lyme borreliosis is a frequent disease, which is spread by ticks, and which can cause symptoms related to skin, cardiovascular system, central nervous system and musculoskeletal system. The testing for Lyme borreliosis is based on blood testing, which is expensive and rarely leads to a convincing diagnosis. In this register study with data from 15.722 patients, we explore the frequency of testing in patients with suspected Lyme borreliosis and where tests are ordinated from. Symptoms resulting in testing for Lyme borreliosis, incl lyme arthritis, and the resulting diagnosis are also explored in order to investigate the indication for and relevance of testing for Lyme borrelioses.

Tilde Müller, Bente Jensen, Henning Loch

Danish Rheumatologic Biobank – the Biomarker protocol

Danish Rheumatologic Biobank is a national biobank for patients with inflammatory arthritis. The vision is to facilitate identification of new biomarkers, aiming to improve diagnostics and predict treatment effects, side effects, and course of disease. Professor Merete Lund Hetland was one of the initiators of Danish Rheumatologic Biobank, which was established in May 2015 and currently holds approximately 8,000 blood samples. Through the Biomarker protocol, many research questions regarding personalized medicine are addressed in collaboration with researchers in Denmark and abroad.

Merete Lund Hetland, Bente Glinborg

Trust, ethnicity and low back pain (TRU-E-SPINE)

Back disorders are the third most common disorders in Denmark and are more frequent in patients with Turkish heritage compared to patients with other ethnical heritage. The aim of the study is to develop, conduct and evaluate an initiative focusing on patients of Turkish ethnicity with back pain. The intervention is inspired by psychoeducation and aims to reduce the experience of back pain. The project is a collaboration with Research Centre for Migration, Ethnicity and Health, University of Copenhagen.

Bente Appel Esbensen

Improved monitoring and prediction of clinical response and disease course during golimumab therapy of patients with axial spondyloarthritis: The clinical utility of whole-body MRI, diffusion-weighted MRI, conventional MRI of sacroiliac joints and spine, and high-sensitive CRP and other soluble biomarkers of joint inflammation and damage (MANGO)

This study aims to investigate the applicability of conventional whole body and diffusion-weighted MR-scans as well as new biochemical methods to predict treatment response and course of disease in patients with spondyloarthritis treated with golimumab. The study has a longitudinal cohort design and is part of Simon Krabbe's PhD project. It also includes an evaluation of a new questionnaire (ASAS health

index) and a comparison with other questionnaires about disease activity and function.

Susanne Juhl Pedersen, Simon Krabbe, Mikkel Østergaard

Pregnancy and rheumatoid arthritis

This study investigates genetic factors and their effect on pregnancies among women with rheumatoid arthritis. Blood is drawn before and after pregnancy. The study is carried out in collaboration with midwives at Copenhagen University Hospital – Rigshospitalet, and researchers from USA.

Merete Lund Hetland

The efficacy and safety of adding tocilizumab to methotrexate and intraarticular glucocorticoid treatment in early rheumatoid arthritis. A randomized, double-blinded, placebo-controlled trial (Dan-ACT)

It is known that patients with rheumatoid arthritis have increased risk of irreversible joint damage. The results of conventional conservative treatment strategies have been disappointing. The literature indicates that early treatment initiation and a treatment strategy focusing on inflammatory control by use of both conventional and biological drugs better prevent loss of function compared to conventional treatment alone. This randomized study with newly diagnosed patients with rheumatoid arthritis tests if treatment with tocilizumab in addition to methotrexate and intraarticular glucocorticoid injections improves inflammatory control and prevents development of erosions compared to an identical treatment without tocilizumab. The study is carried out in collaboration with other departments of rheumatology in Denmark.

Merete Lund Hetland, Mikkel Østergaard

Pregnancy and TNFi in women with inflammatory arthritis

The aim of this project is to investigate how medical treatment and disease activity during pregnancy affects the chance of giving birth to a healthy child in patients with rheumatoid arthritis and other inflammatory rheumatic diseases. Little is known about TNF-inhibitors in this context, and our primary focus is therefore on TNF-inhibitors. The project is a register-based cohort study with data from Danish, Swedish and Icelandic registries covering information on diagnosis, treatment, socioeconomic status etc. It is conducted in collaboration with midwife Ane Rom and researchers at Karolinska Institutet

Anne Emilie Secher, Merete Lund Hetland, Bente Glintborg

Long-term efficacy of a 2-year MRI guided treatment strategy on disease activity, imaging progression, physical function and quality of life in patients with rheumatoid arthritis (RA) – Follow up study year 3, 4, 5 and 10 of the IMAGINE cohort (IMAGINE-more)

The IMAGINE-more study is a follow up on the IMAGINE-RA study, which was a randomized clinical study investigating if the current treatment strategy and course of treatment were improved when using MR-scans in addition to traditional clinical and biochemical methods. Clinical remission and erosive progression evaluated with X-ray were the primary endpoints.

In an open observational study it is now investigated if two years with an MR-guided treatment strategy has a positive effect on remission rate, progression of erosive joint damage, functional level and quality of life during 10-years follow up in patients with rheumatoid arthritis and low disease activity/remission.

Signe Møller-Bisgaard, Merete Lund Hetland, Lykke Midtbøll Ørnbjerg, Mikkel Østergaard

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JOINT RESOURCES - an interdisciplinary programme of physical activity and sedentary behavior in patients with rheumatoid arthritis

This research programme is a collaboration with Center for Clinical Research and Prevention, Bispebjerg Hospital and The University Hospitals Centre for Health Research. The project focuses on physical activity, fatigue, and sleep as well as reduction of sedentary behavior in patients with rheumatoid arthritis. The programme includes both qualitative studies, a cross-sectional study, two randomized controlled studies, and health economic analyses.

Bente Appel Esbensen, Tanja Thomsen, Merete Lund Hetland

The prognosis for rheumatic diseases in Denmark

By connecting data from DANBIO to other national registries this series of register studies are designed to explore:

- 1) Effect of biological DMARDs in patients with rheumatoid arthritis and spondyloarthritis. The primary focus is course of treatments starting from 2007 and later. The effect of medical treatments which were first choice for the specific group of patients according to recommendations by RADs.
- 2) Safety of biological DMARDs in patients with rheumatoid arthritis and spondyloarthritis
- 3) Switch from biological DMARDs in patient with rheumatoid arthritis, psoriatic arthritis and spondyloarthritis
- 4) Predictive value of different parameters related to patient characteristics, comorbidities etc. with respect to treatment effect, safety and switch.

Merete Lund Hetland, Mikkel Østergaard, Bente Glintborg

OMERACT MRI in arthritis working group

In this international collaboration under the auspice of OMERACT, MR-based effect parameters are being developed and evaluated for their use in clinical, randomized, controlled studies and clinical cohorts of patients with rheumatoid arthritis, psoriatic arthritis, spondyloarthritis and osteoarthritis of the hand.

Mikkel Østergaard, Marie Wetterslev, Simon Krabbe, René Poggenborg, Susanne Juhl Pedersen

Predictive value of MRI in rheumatoid arthritis

The predictive value of MRI in relation to progression of structural joint damages is explored in several international, randomized clinical studies of patients with early and established rheumatoid arthritis.

Mikkel Østergaard

The OMERACT ultrasound working group

In this international collaboration under the auspice of OMERACT, US-based effect parameters are developed and evaluated for use in clinical, randomized, controlled studies and clinical cohorts of patients with rheumatoid arthritis, psoriatic arthritis, spondyloarthritis, giant cell arteritis and gout.

Lene Terslev, Sara Nysom Christiansen, Mads Ammitzbøll-Danielsen

How to get from the Multidimensional Health Assessment Questionnaire (MDHAQ) to Stanford Health Assessment Questionnaire Disability Index scores in patients with rheumatoid arthritis, psoriatic arthritis and axial spondyloarthritis: development and validation of a conversion algorithm.

HAQDI is a health assessment questionnaire used to evaluate disability in patients with rheumatoid arthritis based on 20 questions related to their ability to perform activities of daily living. However, patients ask for a less time-consuming evaluation tool. MDHAQ is a modified and significantly less time-consuming version of HAQ-DI which is now implemented in the Danish quality registry, DANBIO. Since HAQ-DI is still used in other European quality registries, this study was initiated in order to develop and validate an algorithm to interconvert HAQ-DI and MDHAQ scores to enable comparison of data across databases. The model is developed with data from the DANBIO from 2015-2017 and includes relevant demographic, clinical and patient reported outcomes.

Lykke Midtbøll Ørnbjerg, Dorte Vendelbo Jensen, Merete Lund Hetland

Validation and assessment of minimally clinically important difference of the unadjusted Health Assessment Questionnaire in a Danish cohort: uncovering ordinal bias.

This study investigates the minimally clinically important difference of HAQ-DI in patients with rheumatoid arthritis. Data comes from DANBIO, concerns patients who are followed at Center for Rheumatology and Spine Diseases in Glostrup and is analyzed by means of stratification based on treatment response (worsened, no effect, minimal improvement, improvement). The minimally clinically important difference in HAQ-DI is defined and the median change in the group of subjects with minimal improvement. Finally, a psychometric validation of HAQ-DI is performed using the Rasch model.

Lykke Midtbøll Ørnbjerg, Merete Lund Hetland.

Outcome measures in rheumatology – interventions for self-management targeted people with inflammatory arthritis: a systematic review of outcome domains and measurement instruments

This study aims is to identify and map relevant outcome domains and outcome measurement instruments in previous studies measuring the effect of self-management interventions targeting people with IA through an informative systematic literature review as recommended by the 'Outcome Measures in Rheumatology' (OMERACT), and the 'Core Outcome Measures in Effectiveness Trials' (COMET) initiatives.

Charlotte Werdahl Hansen, Pernille Cromhout, Bente Appel Esbensen

Publications

In 2021, COPECARE authored 103 original papers, 67 conference abstracts and a number of other publications:

PhD dissertations

1. **Psoriasis and peripheral psoriatic arthritis - association between imaging inflammation, pain and tenderness, disability, and health-related quality of life.** / Felbo, Sara Helena Kamp. Faculty of Health and Medical Science., University of Copenhagen, 2021;149 .
2. **Non-pharmacological treatment of sleep disturbances or sleep disorders in people with inflammatory arthritis.** / Latocha, Kristine Marie. Faculty of Health and Medical Science., University of Copenhagen, 2021;190 .
3. **Magnetic resonance imaging of the sacroiliac joints in the differential diagnosis of axial spondyloarthritis - a comparison with various control groups.** / Seven, Sengül. Faculty of Health and Medical Science., University of Copenhagen, 2021; 153.
4. **Axial spondyloarthritis: Course of clinical and magnetic resonance imaging findings after dose changes in biologic therapy.** / Wetterslev, Marie. Faculty of Health and Medical Science., University of Copenhagen, 2021; 135.

Books

1. **Forskningsmetode for sundhedsprofessionelle.** / Esbensen, Bente Appel; Kjærgaard, Jesper; Juhl, Mette.
1 ed. Frydenlund, 2021; 256.

Contributions to books/anthology

1. **Ultrasound in rheumatoid arthritis.** / Hammer, Hilde Berner; Terslev, Lene. Musculoskeletal Ultrasound in Rheumatology Review. 2. ed. Springer Cham, 2021; 343-365.

2. **Imaging in spondyloarthritis - Magnetic Resonance Imaging.** / Mathew, Ashish Jacob; Østergaard, Mikkel.
Rheumatology Clinics: Spondyloarthritis. red. / Rohini Handa; Aman Sharma. New Delhi, India: Evangel Publishing, 2021; 92.
3. **Bevægeapparatets sygdomme.** / Nielsen, Christoffer Tandrup. Praktisk Medicin: Medicinsk opslagsværk for sundhedsprofessionelle. 2021.
4. **Arthritis imaging: signs/figures/drawings/patterns.** / Becce, Fabio; Boesen, Mikael; Eshed, Iris; Feydy, Antoine; Hermann, Kay-Geert; Herregods, Nele; Jaremko, Jacob L.; Lecouvet, Frédéric; Maas, Mario; Mascarenhas, Vasco; Reijnierse, Monique; Rennie, Winston J.; Sudol-Szopińska, Iwona; Sutter, Reto; Teh, James; Vanhoenacker, Filip; Verstraete; Koenraad; Baraliakos, Xenofon; Carlile, Narath; Carron, Philippe; Conaghan, Philip G.; DeJaco, Christian; Elewaut, Dirk; Haavardsholm, Espen A.; Kloppenburg, Margreet; Malattia, Clara; Maksymowych, Walter P.; Terslev, Lene; Østergaard, Mikkel; Van den Bosch, Filip; Weisman, Michael H.
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Original papers

1. **Calibration-free concentration analysis for quantification of anti-drug specific antibodies in polyclonal positive control antibodies and in clinical samples.** / Aniol-Nielsen, Christina; Toft-Hansen, Henrik; Dahlbäck, Madeleine; Nielsen, Claus Henrik; Solberg, Helene. I: Journal of Immunological Methods, 2021; 497: 113002.
2. **Lordosis distribution index in short-segment lumbar spine fusion - can ideal lordosis reduce revision surgery and iatrogenic deformity?** / Bari, Tanvir Johanning; Heegaard, Martin; Bech-Azeddine, Rachid; Dahl, Benny; Gehrchen, Martin. I: Neurospine, 2021; 18: 543-553.
3. **Facilitators and barriers in diagnosing rheumatoid arthritis as described by general practitioners: a Danish study based on focus group interviews.** / Baymler Lundberg, Anne Sofie; Esbensen, Bente Appel; Jensen, Martin Bach; Hauge, Ellen Margrethe; Thurah, Annette de. I: Scandinavian Journal of Primary Health Care, 2021; 39: 222-229.
4. **Outcomes of decompression without fusion in patients with lumbar spinal stenosis and substantial back pain.** / Bech-Azeddine, Rachid; Fruensgaard, Søren; Andersen, Mikkel; Carreon, Leah Y. I: Journal of Neurosurgery: Spine, 2021; 34: 553-556.

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6. **Variants in BANK1 are associated with lupus nephritis of European ancestry.** / Bolin, Karin; Imgenberg-Kreuz, Juliana; Leonard, Dag; Sandling, Johanna K; Alexsson, Andrei; Pucholt, Pascal; Haarhaus, Malena Loberg; Almlöf, Jonas Carlsson; Nititham, Joanne; Jönsen, Andreas; Sjöwall, Christopher; Bengtsson, Anders A; Rantapää-Dahlqvist, Solbritt; Svenungsson, Elisabet; Gunnarsson, Iva; Syvänen, Ann-Christine; Lerang, Karoline; Troldborg, Anne; Voss, Anne; Molberg, Øyvind; Jacobsen, Søren; Criswell, Lindsey; Rönnblom, Lars; Nordmark, Gunnel. I: *Genes and Immunity*, 2021; 22: 194-202.

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8. **Consensus-based semi-quantitative ultrasound scoring system for gout lesions: Results of an OMERACT Delphi process and web-reliability exercise.** / on the behalf of the OMERACT Ultrasound working group.I: *Seminars in Arthritis and Rheumatism*, 2021; 5: 644-649.

9. **Gradual reduction of tophaceous deposits during urate-lowering therapy.** / Christiansen, Sara Nysom; Terslev, Lene; Østergaard, Mikkel; Slot, Ole. I: *Joint Bone Spine* 2021; 105049.

10. **Ultrasound for the diagnosis of gout-the value of gout lesions as defined by the Outcome Measures in Rheumatology ultrasound group.** / Christiansen, Sara Nysom; Østergaard, Mikkel; Slot, Ole; Fana, Viktoria; Terslev, Lene. I: *Rheumatology (Oxford, England)*, 2021; 60: 239-249.

11. **Diagnostic accuracy of vascular ultrasound in patients with suspected giant cell arteritis (EUREKA): a prospective, multicentre, non-interventional, cohort study.** / Chrysidis, Stavros; Døhn, Uffe Møller; Terslev, Lene; Fredberg, Ulrich; Lorenzen, Tove; Christensen, Robin; Larsen, Knud; Diamantopoulos, Andreas P. I: *The Lancet Rheumatology*, 2021; 3: e865-e873.

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Collaborations

Great collaborations with researchers from all over the world have built the fundament for many of our research projects. The two sections below provide an overview of some of our current collaboration partners.

National collaborators

- All rheumatological departments in Denmark
- Bio- and Genome Bank Denmark, the Secretariat (Estrid Høgdall, Astrid Munk Pedersen)
- Board of Management, Copenhagen University Hospital – Rigshospitalet (Susanne Poulsen)
- CASTLE – Cancer Survivorship and General Late Effects, Danish Comprehensive Cancer Center, Department of Oncology, Centre for Cancer and Organ Diseases, Copenhagen University Hospital – Rigshospitalet (Katrine Bjerre Løppenthin)
- Center for Clinical Research and Prevention, USCF (Mette Aadahl)
- Center of Head and Orthopaedics, Copenhagen University Hospital – Rigshospitalet (Martin Magelund, Jeanne Devantier)
- Copenhagen Palliative Team for Children and Adolescent and Paediatric Oncology Research Laboratory (Bonkolab), The Juliane Marie Centre, Copenhagen University Hospital – Rigshospitalet (Nanna Maria Hammer)
- Danish Hospital for Rheumatic Diseases, Sønderborg (Jette Primdahl)
- The Danish Rheumatology Database, DANBIO (the DANBIO secretary and steering committee)
- Danish Center for Sleep Medicine, Copenhagen University Hospital – Rigshospitalet (Poul Jørgen Jennum)
- Department of Bacteria, Parasites and Fungi, Statens Serum Institut, Copenhagen (Andreas Petersen)
- Department of Cardiology, Herlev-Gentofte Hospital, Hellerup (Louise Bruun Østergaard)
- Department of Cardiology, Zealand University Hospital, Roskilde (Bianca Bech)
- Department of Clinical Biochemistry, Copenhagen University Hospital – Rigshospitalet (Niklas Rye Jørgensen)
- Department of Clinical Epidemiology, Aarhus University Hospital (Mette Nørgaard, Frank Mehnert, Nickolaj Risbo Kristensen, Henrik Toft Sørensen)
- Department of Clinical Immunology, Næstved Hospital (Ole Birger Pedersen)
- Department of Dermatology and Allergy, Herlev and Gentofte Hospital (Lone Skov, Claus Zachariae)
- Department of Infectious Diseases, Hvidovre Hospital (Thomas Benfield)
- Department of Obstetrics, The Juliane Marie Centre, Copenhagen University Hospital – Rigshospitalet (Mette Kiel Smed)
- Department of Oncology, Herlev and Gentofte Hospital (Julia Johansen)
- Department of Ophthalmology, Copenhagen University Hospital – Rigshospitalet, Glostrup (Steffen Hamann, Steffen Heegaard)
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- Department of Radiology, Herlev and Gentofte Hospital (Henrik Thomsen, Jakob Møller, Kasper Gosvig)
- Department of Radiology, Odense University Hospital (Trine Torfing)
- Department of Radiology, Copenhagen University Hospital – Rigshospitalet, Glostrup (Anne Duer)
- Department of Radiology, Aarhus University Hospital (Anne Grethe Jurik)
- Department of Regional Health Research (Vibeke Andersen)
- Rigshospitalet, Center of Head and Orthopedics, Department of Orthopedic Surgery, University of Copenhagen, Herlev and Gentofte Hospital (Anders Odgaard)
- Herlev Acute, Critical and Emergency Care Science Unit, Department of Anaesthesiology, Herlev and Gentofte Hospital (Thordis Thomsen)
- Mental health services in the Capital Region of Denmark, Mental Health Centre Glostrup, University of Copenhagen (Julie Midtgaard)
- Patient research partners
- The Danish Clinical Quality Program– National Clinical Registries (RKKP) (Elisabeth Svensson, Katja Løngaard)
- The Juliane Marie Centre, Copenhagen University Hospital – Rigshospitalet (Ane Rom a.o.)
- The National Research Centre for the Working Environment (Jakob Bjørner)
- The Parker Institute, Frederiksberg (Robin Christensen, Lars Erik Kristensen, Simon Tarp a.o.)
- VIVE (Jakob Kjellberg)
- Zitellab ApS (Niels Steen Krogh a.o.)

International collaborators

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- Amsterdam Rheumatology & Immunology Center, Academic Medical Center, Amsterdam UMC, VU University medical centre Amsterdam, Department of Rheumatology, Amsterdam, The Netherlands (Ronald van Vollenhoven, Irene van der Horst-Bruinsma, Marleen van de Sande)
- Biorix.si and the Department of Rheumatology, University Medical Centre, Ljubljana, Slovenia (Matja Tomsic, Ziga Rotar)
- Center of Rheumatic Diseases, University of Medicine and Pharmacy, Bucharest, Romania (Catalin Codreanu)
- Charité – Universitätsmedizin Berlin, Berlin, Germany
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 2. Department of Radiology (Kay-Geert Hermann, Torsten Diekhoff)
- Children’s Hospital Oakland Research Institute, Oakland, Californien (Damini Jawaheer)
- Cochrane Tobacco Addiction Group, The Nuffield Department of Primary Care Health Sciences, University of Oxford, UK
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- Department of Radiology, Tel Aviv, Israel (Iris Eshed)

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- East Tallinn Central Hospital, Department of Rheumatology, ERS Biologic Therapy Register, Estonia (Karin Laas)
- Epidemiology Group, School of Medicine, Medical Science and Nutrition, University of Aberdeen, Aberdeen, United Kingdom (Gareth Jones, Gary Macfalane)
- Faculty of Health Studies, VID, Norway (Heidi Andersen Zangi)
- German Rheumatism Research Centre, Berlin, Tyskland (Joachim Listing, Anja Strangfeld)
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- Instituto de Salud Musculoesquelética, Madrid, Spain (Loreto Carmona)
- Landspítali University Hospital, Reykjavík, Iceland (Gerdur Gröndal, Björn Gudbjörnsson)
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- National Advisory Unit on Rehabilitation in Rheumatology, Diakonhjemmet Hospital, Oslo, Norway (Heidi Andersen Zangi)
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- Reuma.pt registry and Instituto de Medicina Molecular, Faculdade de Medicina, Universidade de Lisboa, Portugal (Maria José Santos, Anabele Barcelos)
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- University of Torino, Italien (Annamaria Iagnocco)
- University of Toronto, Canada (Vinod Chandran, Dafna Gladman)
- University Rheumatologists, Rush University Medical Center, Chicago, USA (Ted Pincus)
- UWE Bristol, United Kingdom (Mwidi Ndosi, Emma Dures, Anne-Marie Tetsche Sweeney)

Highlights of the year

Scandinavian Congress of Rheumatology Award Denmark

In early September 2021, a group from COPECARE attended the Scandinavian Congress of Rheumatology in Ålesund, Norway. This was the first real congress after corona shutdowns, and it was indeed a great pleasure to meet with colleagues, to be scientifically updated, exchange ideas and network. The scientific content was very good and COPECARE delivered several presentations.

From our perspective, the key event took place when professor Lene Terslev was awarded the Scandinavian Congress of Rheumatology award for her research within ultrasonography in rheumatology. Lene is truly an expert in this field and it was a proud day for her and for us.

Finally, as indicated by the photos, we were fortunate to have time for social activities whilst enjoying the beautiful weather and scenic landscape.



1) Lene Terslev, 2) Lykke Midtbøll Ørnbjerg & Sara Nysom Christiansen, 3) Sophine Boysen Krintel, Lykke Midtbøll Ørnbjerg & Mikkel Østergaard, 4) Lene Terslev, Bente Appel Esbensen, Merete Lund Hetland & Mikkel Østergaard

PhD defence – Sengül Seven

On September 15th, physician and specialist in rheumatology, Sengül Seven, defended her PhD thesis titled “Magnetic resonance imaging of the sacroiliac joints in the differential diagnosis of axial spondyloarthritis - a comparison with various control groups”.

The objective of the PhD project was to investigate the utility of different established and new SIJ MRI scoring methods for improving the differentiation of axial spondyloarthritis from other conditions that may mimic axial spondyloarthritis on MRI.

The PhD project was based on a prospective, cross-sectional study, which included patients with axial spondyloarthritis (n=41) and 6 control groups consisting of women with (n=46) and without (n=14) post-partum pain, patients with lumbar disc herniation (n=25), cleaning staff (n=26), long distance runners (n=23) and healthy men (n=29). MRI of the SIJs was performed and assessed for the presence of SIJ lesions, such as bone marrow edema, fat lesion, sclerosis, erosion, backfill and ankylosis. The images were scored according to the SPARCC scores for inflammation and structural lesions, lesion combination scores as well as lesion depth or lesion extent scores.

Overall, the PhD project demonstrated that distinguishing patients with axial spondyloarthritis from women with post-partum pain was particularly challenging, while all other control groups were more easily differentiated from patients with axial spondyloarthritis. Bone marrow edema showed low diagnostic utility, regardless of scoring method, when comparing axial spondyloarthritis with women



Michael Kjær, Susanne Juhl Pedersen, Sengül Seven, Anne Gitte Loft, Mats Geijer, Mikkel Østergaard

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with post-partum pain. However, when excluding the post-partum women, BME showed better diagnostic utility. In contrast, fat lesion, especially when deep, and erosion, especially when extensive, overall performed better in differentiating axial spondyloarthritis from control groups, while backfill and ankylosis were highly specific for axial spondyloarthritis, irrespective of scoring method.

Since her PhD defence, Sengül has moved on with her career as a rheumatologist in a private practice.

PhD supervisors: Mikkel Østergaard (principal supervisor), Susanne Juhl Pedersen.

Assessment committee: Professor Michael Kjær, MD, DMSc, Department of Orthopedic Surgery, Bispebjerg and Frederiksberg Hospital; Professor Mats Geijer, MD, PhD, Department of Radiology, Sahlgrenska Academy, University of Gothenburg; Associate Professor Anne Gitte Loft, MD, DMSc Department of Rheumatology, Aarhus University Hospital.

PhD defence – Sara Helena Kamp Felbo

On the 2nd of November, Sara Helena Kamp Felbo defended her PhD thesis “Psoriasis and peripheral psoriatic arthritis - association between imaging inflammation, pain and tenderness, disability, and health-related quality of life”. The aim of this thesis was to investigate the extent of and associations between musculoskeletal pain and tenderness, clinical features, inflammation detected by imaging, and patient-reported outcomes (PROs) of physical and mental health in patients with PsO and PsA. This was investigated through four papers.

The first two papers investigated musculoskeletal pain in patients with PsO. The first paper was based on a national survey including 561 patients with PsO, comparing the characteristics of patients with PsO with self-reported MSK pain to patients with PsO without MSK pain and patients with diagnosed PsA. We found that 45% of patients with PsO had MSK pain now or within the past 12 months, and that three out of four (72%) patients with MSK pain had never been examined by a rheumatologist. Health-related quality of life (HRQoL) in these patients was impaired compared to patients with PsO without MSK pain and at the same level as patients with diagnosed PsA. In the second paper, 126 patients from the survey were examined clinically and with ultrasound to evaluate if the self-reported MSK pain was related to inflammation. Tenderness of joints, entheses and fibromyalgia points were more frequent than in patients with PsO with compared to without MSK pain, swollen joints and dactylitis were not. However, ultrasound synovitis was more frequent in patients with MSK pain. Therefore, almost twice as many patients could be classified as having PsA when adding ultrasound inflammation to clinical evaluation in the classification criteria. In contrast, screening questionnaires for identification of patients with PsA were found of little value, as sensitivities and specificities were low.

In the third paper, correlations between MRI and ultrasound inflammation and tender joints were examined in patients with established, active PsA, both on patient and joint level. No correlations at patient level were found. At joint-level, joint tenderness did not reflect inflammation by ultrasound or MRI, whereas joint swelling reflected inflammatory imaging findings better. In patients with high levels of overall pain, disability or low self-reported mental health, associations between tenderness and

imaging inflammation were particularly low, indicating an impact of other parameters than local inflammation on tenderness in these patients, e.g. via central sensitization.

In the fourth and final paper, ultrasound lesions in the key PsA feature dactylitis were examined. Subcutaneous changes in combination with synovitis and tenosynovitis were most frequent, but other lesions including enthesitis of both flexor and extensor tendons and paratenonitis were also found. When all lesions were summed, the score was higher in tender compared to non-tender dactylitis, indicating that tenderness here reflects a higher inflammatory activity.

In conclusion, the findings of the thesis support the use of imaging in both diagnosis and evaluation of disease activity in PsA, as clinical signs of disease may be scarce, especially in early PsA, and tenderness may not be related to local inflammation.

PhD supervisors: Mikkel Østergaard (principal supervisor), Lene Terslev and Inge Juul Sørensen.

Assessment committee: Professor Claus Henrik Nielsen, MD, PhD, MSc, Department of Odontology, University of Copenhagen, Associate professor Heidi Lausten Munk, MD, PhD, Department of Rheumatology, Odense University Hospital, Associate professor Ingrid Möller Parera, MD, PhD, Poal Institute of Rheumatology, International University of Catalunya, University of Barcelona.



Claus Henrik Nielsen, Ingrid Möller Parera, Heidi Lausten Munk, Sara Helena Kamp Felbo, Lene Terslev, Mikkel Østergaard

PhD defence – Marie Wetterslev

“Axial spondyloarthritis: Course of clinical and magnetic resonance imaging findings after dose changes in biologic therapy” is the title of physician Marie Wetterslev’s PhD project, which she defended on November 23rd, 2021. The overall aim of the PhD project was, in patients with axial spondyloarthritis (axSpA), to study the course of clinical and magnetic resonance imaging (MRI) findings after tapering or initiation of biological therapy and investigate potential predictors of successful tapering. This was done within four longitudinal studies – two cohort studies including patients with axSpA and two methodology studies in collaboration with the OMERACT MRI in Arthritis Working Group investigating whole-body MRI (WB-MRI) methods in the knee and hip/pelvis region in patients with SpA.

The main study was a prospective quality study from routine care in the Capital region of Denmark where 109 axSpA patients in clinical remission were stepwise dose tapered until withdrawal according to a systematical dose adjustment algorithm. Besides patient reported outcomes and clinical measures, patients had sequential MRIs and radiographs obtained until 2-years follow-up. It was concluded that tapering of axSpA patients in clinical remission in routine care was feasible in approximately half of the patients, whereas withdrawal was not possible. Patients regained clinical remission after flare, and only minimal structural progression on MRI and radiographs were seen at 2-years follow-up. Lower physician global visual analogue scale (VAS) was identified as an independent predictor for successful tapering.

In the second study, three preliminary versions of an axSpA MRI sacroiliac joints (SIJ) Composite Structural Damage Score (CSDS) were created and calculated based on the Spondyloarthritis Research Consortium of Canada (SPARCC) scores for erosion, backfill and ankylosis. The CSDSs were exploratively tested in a 5-year follow-up study in patients with axSpA initiating biological therapy.

Two of three composite scores for MRI SIJ structural damage showed pronounced progression and moderate responsiveness, indicating that they may be usable for assessing structural changes over time in axSpA clinical trials.

The third and fourth studies investigated interreader reliability, correlation between methods and sensitivity to change in two scorings systems for assessments of inflammation in WB-MR images of the knee region and the hip and pelvis region, respectively. Inflammation was overall reliably assessed on WB-MRIs evaluated by experienced readers with the scoring systems MRI-WIPE, KIMRISS and HIMRISS, which after further validation may be useful outcome tools in SpA clinical trials.

Since the submission of her thesis, Marie has started her specialty training in Internal Medicine and Rheumatology. Alongside, she works on projects related to her PhD studies and reads images in EuroSpA.

PhD supervisors: Professor Mikkel Østergaard, MD, PhD, MDSc (principal supervisor), Professor Merete Lund Hetland, MD, PhD, MDSc, Inge Juul Sørensen, MD, PhD, Susanne Juhl Pedersen, MD, PhD and Cecilie Heegaard Brahe, MD, PhD.

Assessment committee: Professor Michael Kjær, MD, DMSc, Department of Orthopedic Surgery, Bispebjerg and Frederiksberg Hospital, and Department of Clinical Medicine, Faculty of Health and Medical Science, University of Copenhagen, Professor Kay-Geert Hermann, MD, Dr. med, Department

of Radiology, Professor Oliver Hendricks, MD, PhD, Danish Hospital for Rheumatic Diseases, Sønderborg, and Institute for Regional Health Research, University of Southern Denmark.



Mikkel Østergaard, Inge Juul Sørensen, Susanne Juhl Pedersen, Marie Wetterslev, Cecilie Cornelia Heegaard Brahe

PhD defence – Kristine Marie Latocha

The last PhD presentation in 2021 took place December 17th when nurse Kristine Marie Latocha defended her work “Non-Pharmacological Treatment of Sleep Disturbances or Sleep Disorders in People with Inflammatory Arthritis”.

The three studies relied on 1) a systematic review and meta-analysis of the evidence of non-pharmacological interventions targeting sleep disturbances or disorders in people with inflammatory arthritis, 2) a randomised controlled trial (RCT) investigating the effect of cognitive behavioural therapy for insomnia (CBT-I) in people with rheumatoid arthritis (RA) and 3) a qualitative evaluation-study describing experiences of CBT-I in people with RA and how the components of CBT-I were incorporated in sleep management.

In the evidence synthesis any sleep domain assessed with a validated measurement was considered of primary interest and secondarily we assessed outcomes for inflammatory arthritis. In the RCT the participants were allocated 1:1 to six weeks CBT-I or usual care (no treatment for insomnia). Data were collected at baseline, week 7, and week 26. Measurements used to collect data for primary and key secondary outcomes were polysomnography (PSG) and patient reported outcome measures (PROMs). In the qualitative study, we conducted semi-structured interviews with participants who had received CBT-I in the RCT. The analysis was based on Braun and Clarke’s reflexive thematic method.

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The meta-analysis demonstrated that nonpharmacological interventions targeting sleep disturbances or insomnia is promising and potentially highly effective, but not yet with convincing evidence. In relation to the RCT, we found no effect of CBT-I on the primary outcomes; sleep efficiency measured by PSG at week 7 compared to usual care. In relation to the key secondary outcomes of insomnia, sleep quality, fatigue, RA impact of disease, and depressive symptoms measured by PROMs, we found a statistically and clinically significant mean difference between the groups, all in favour of CBT-I. Further we found that CBT-I improved patient global assessment, and pain, but not disease activity or physical function, compared to usual care. In the qualitative study, five themes emerged: (1) When knowledge contributes to an altered perception of sleep, (2) Overcoming habits and perceptions to accelerate sleep onset, (3) The sleep window of challenges in learning how to sleep right, (4) Relaxation becomes a behavioural habit and goes beyond sleep, and (5) Break the cycle and regain control.

This PhD emphasises that there are potentially several effective non-pharmacological options for treating sleep disorders and insomnia in people with inflammatory arthritis. CBT-I has no effect on sleep efficiency measured by PSG in people with RA. However, CBT-I can improve insomnia, sleep quality, fatigue, depressive symptoms, and pain measured by PROMs, and the effect of CBT-I increases over time. Patients describe CBT-I as demanding but at the same time meaningful. Health professionals should be aware of how CBT-I is perceived by the patients and when to provide the necessary support.

Since Kristine's PhD defence she has continued working in COPECARE as a postdoc on the feasibility study "INSELMA – An interdisciplinary nurse coordinated self-management intervention to patients with inflammatory arthritis and substantial disease impact".



Tom Møller, Bente Appel Esbensen, Kristine Marie Latocha, Oliver Hendricks, Mikkel Østergaard

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 Assessment committee: Tom Møller, PhD, MPH, RN, Senior Researcher; Oliver Hendricks, PhD, MD, Professor; Jason Ellis, PhD, MSc Psychology, Professor.

EuroSpA Imaging Workshop

Within the EuroSpA collaboration, a group of researchers are focusing on the importance of MRI for diagnostic and prognostic purposes within SpA and axSpA as well as the use of MRI for disease monitoring.

To ensure comparability across EuroSpA member countries, all members of the EuroSpA Imaging group have completed the same online training. To further enhance comparability, COPECARE hosted a EuroSpA Imaging workshop, which took place September 24th-26th.

The workshop combined presentations of current knowledge and experience with hands-on MRI training, quizzes and other relevant topics such as data entry.

It was great and educational to have the EuroSpA Imaging team gathered for this workshop, which gave rise to many relevant discussions and exchange of knowledge, and ended with a nice dinner in great company.



EuroSpA Imaging dinner: Nora Borislavova Valdimirova, Karlo Pintaric, Marie Wetterslev, Anna Enevold Fløistrup Hadsbjerg, Sengül Seven, Kristyna Bubova, Lykke Midtbøll Ørnbjerg, Ziga Snoj



EuroSpA Imaging dinner: Michael Nissen, Simon Krabbe, Susanne Juhl Pedersen, Isabel Martinez Tejada, Karel Gorican, Stephanie Wichuk, Simon Horskjær Rasmussen, Mikkel Østergaard, Ashish Jacob Mathew, Manouk de Hooge

OUTRO

Thank you and goodbye 2021

Despite the corona pandemic, 2021 has been an interesting and busy year and we look forward to the continuation of many interesting projects and great collaborations as well as the beginning of new ones.



Thank you to everyone who contributed in the process of composing the report.