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FACULTY OF HEALTH AND MEDICAL SCIENCES

798: Patient-reported outcomes in bladder cancer; a multicentre randomized controlled trial – a study design

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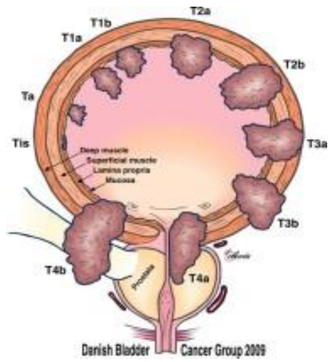
OBJECTIVE

The aim of this study is to determine the short term effect of using patient-reported outcomes during chemotherapy or immunotherapy.



INTRODUCTION

While the use of Patient-Reported Outcomes (PROs) is becoming more widespread throughout the health care system, we still know little about the impact of using PROs on specific cancer diagnoses. In the present study we focus on the use of PROs in patients with muscle-invasive bladder cancer undergoing medical oncological treatment. With the promising introduction of immunotherapy in this patient group the character of this disease may change and as a consequence hereof change patient experienced symptoms. This enhances the need for methods to measure the quality of life in these patients.

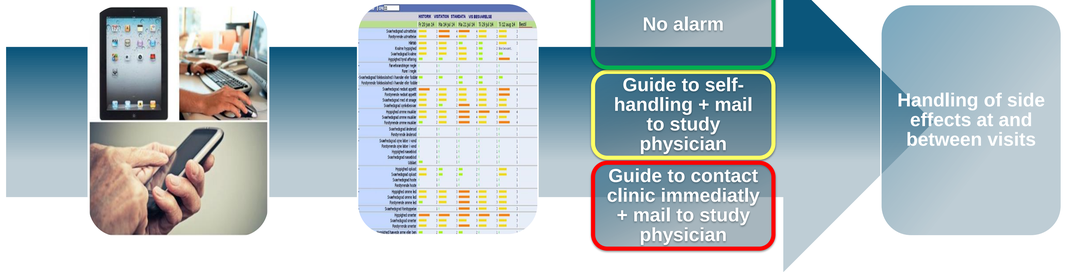


Figure 1. PRO-data collected by tablet, smartphone or computer resulting in green, yellow or red symptoms depending on predefined scores illustrative for physician/nurse.
The 3 PRO categories result in different outcomes/actions by patient or clinic/clinician.

INCLUSION SITES:
- Rigshospitalet & Herlev Hospital
PATIENTS:
- Urothelial cancer, T2-4NxMx
TREATMENT:
- Chemotherapy or immunotherapy
PERIOD:
- September 2018 – January 2020
NUMBER:
- N=230

Standard CTCAE reporting by clinician
+
PRO-CTCAE™
EORTC QLQ-C30
EORTC QLQ-BLM30

Standard CTCAE reporting by clinician

END POINTS:
- Overall survival
- Quality of life
- Hospital admissions
- Rate of completion of chemo-/immunotherapy
- Dose reductions
- PRO-CTCAE™ vs. CTCAE-registration

Figure 2. Study design

METHODS

Intervention/PRO-arm:
Weekly reports from patients on tablet computers with:

- EORTC's QLQ-C30 and BLM-30 (for muscle-invasive bladder cancer) questionnaires.
- Selected PRO-CTCAE™ questions.
- Alert-algorithm: depending on the severity of symptoms an alert will show, guiding the patient on how to handle the given side effect (either self-handling, contact to nurse or physician). Severe symptoms will trigger alerts directly to nurse or physician.

MATERIALS

- 230 bladder cancer patients stages T2-T4NxMx
- Chemo- or immunotherapy for locally advanced or metastatic disease
- Able to handle a tablet computer.
- The study has been approved by The National Data Agency and will be registered on ClinicalTrials.gov. Written informed consent will be obtained from all patients included.

RESULTS

The study will be initiated in September 2018 at Herlev Hospital and Rigshospitalet, Denmark, and is planned to be conducted within 16 months. The initial results of the study are awaited in the beginning of 2020. The hypothesis is that patients in the PRO-arm will have a higher rate of completion of chemotherapy and immunotherapy, fewer admissions to hospital, a higher quality of life, and eventually better survival as compared to the control arm.

PERSPECTIVES

The short term goal is to alleviate bladder cancer patients their troublesome symptoms during cancer treatment while our long term hope is to improve treatment adherence, survival and quality of life.

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