

Protokoltitel	A prospective, multicenter, phase-II trial of ibrutinib plus venetoclax in patients with creatinine clearance ≥ 30 ml/min who have relapsed or refractory chronic lymphocytic leukemia (RR-CLL) with or without TP53 aberrations
Diagnose	CLL, relapsed or refractory
Protokolnummer	VISION/HO141
Danske centre	Rigshospitalet, Odense, Aarhus, Aalborg, Herlev, Holstebro, Esbjerg, Roskilde
Formål, design og resume	<p>The aim of the current trial is to evaluate if combination treatment with venetoclax + ibrutinib in patients with relapsed or refractory chronic lymphocytic leukemia (RR CLL) can lead to MRD negativity, which may induce long lasting remissions for MRD-negative patients randomized to stopping treatment after 15 induction cycles</p> <p>Fit and unfit patients with a creatinine clearance ≥ 30 ml/min with previously treated CLL requiring treatment</p> <p>The primary objective: - Evaluate efficacy of ibrutinib + venetoclax (VI) in terms of proportion of patients fulfilling the criteria for progression free survival (PFS) at 12 months after stopping therapy (27 months after starting treatment) for patients</p>

	randomized to stop treatment (arm B of the study), reinitiated treatment due to MRD positivity not considered progression (see section 13.1 for details).
Hvilke ptt.	Patients with creatinine clearance ≥ 30 ml/min who have relapsed or refractory chronic lymphocytic leukemia (RR-CLL) with or without TP53 aberrations. Som ikke tidligere er behandlet med Venetoclax/Ibrutinib
Hvor mange ptt.	230 pt i alt, på RH: ca. 20
Hvordan	
Hvor længe	Start: 2017 juni, forventet "Last patient first visit" approx. slut 2019. Duration of accrual: 27 month Duration of trial therapy (per patient): 27 months Duration of the follow-up: 7 years Accrual may be interrupted or the trial may be stopped early based on the results of the interim safety analysis or if new scientific data become available which change assessment of risk/benefit.
Særlige dosismodifikationer	Se behandlingsskema. Ramp-up Venetoclax
Særlige in- eller eksklusions kriterier	
Randomisering hvordan:	<ul style="list-style-type: none"> Elektronisk registrering af patient i TOP (https://www.hdc.hovon.nl/top/logon.asp) Pt's inklusions data registreres Patient ID allokeres via TOP Randomisering foregår via TOP efter 15 serier, kun for MRD negative patienter.
Særlige KAT opgaver	Opbevarer og udlv. begge præparater Obs. Biobank prøver hvis pt. underskrive på separat samtykke
Andet	
KAT ansvarlig pro. spl.	Navn: Regina Uhre Tlf. nr: 3545 8953 Navn: Tlf.nr:
Forsøgsansvarlig læge	Navn: Carsten Niemann Tlf. Nr: 35457830