

V. Study assessment table (SCIT)

		HBV testing ²	Pregnancy test ³	Concomitant Medication	ECOG / disease-related B-symptoms	Height / Weight / BSA	Physical examination	Radiological assessment ⁴	ECG / LVEF	Complete blood counts ⁵	Serum chemistry ⁶	Quality of life (QoL) ⁷	FISH cytogenetics, TP53 and IGHV (central lab Ulm)	MRD from peripheral blood (central lab Kiel)	Accompanying scientific program	Bone marrow aspirate/biopsy ⁸	MRD from bone marrow ⁹ (central lab Kiel)	Response assessment	New treatment and survival status	Rituximab	i.v. administration of Bendamustin	i.v. administration of Cyclophosphamid	i.v. administration of Fludarabine and Cyclophosphamid	(serious) adverse events ⁹	
Cycle 1-6	day 1 ¹	(x)	(x)	CONTINUOUS REPORTING		X	O			X	X			X ¹⁰	X ^{11, 12}				X	X	X	X			
	days 2/(3)																					X	X		
	days 8/15/22										O	O													
Interim staging ¹³						X	X	(x)	O	X	X	X		X ¹²		X ¹²			X	X					
Initial response assessment ¹⁴						X	X	(x)	O	X	X	X		X ¹²		X ¹²			X	X					
Final restaging ¹⁵		(x)	(x)			X	X	X	O	X	X			X ¹²		X ¹²	X	X	X	X					
MRD-Staging 1 ¹⁶									O				X	X ¹²	X	X ¹²			X	X					
MRD-Staging 2 [MO13] ¹⁷		(x)				X	X	(x)	O	X	X	X		X ¹²	X	X ¹²			X	X					
MRD-Staging 3 [MO15] ¹⁸		(x)				X	X	(x)	O	X	X	X		X ¹²	X	X ¹²			X	X					
Follow-up until PD ¹⁹		(x)				X	X	(x)	O	X	O	X ²⁰		X ¹²		X ¹²			X	X					
Follow-up after PD ²¹					X			O				X ²⁰						X	X						

10)C1D1 en C2D1; 11) C2D1; 12) bij progressie

X = assessment mandatory, (x) = assessment mandatory in certain patients/situations, O = assessment recommended, but not documented in the CRF.

For all tests in the study a time window of +/- 2 days is appropriate.