Visit	Screening	Baseline	Visit 1 - Treatment	Visit 2 - Treatment	Visit 3 - Assessment	Visit 4 - Midpoint assessment	Visit 5 - Treatment	Visit 6 - Treatment	Visit 7 - Assessment	Visit 8 – End of study assessment
Assessment (Procedure / Activity)	Week -4 (+14 days)	Week -2 (+ 14 days)	Week 0	Week 2 (+ 7 days)	Week 16 (+/- 7 days)	Week 24 (-7 days)[4]	Week 24 (+/- 7 days)	Week 26 (+ 7 days)	Week 36 (+/- 7 days)	Week 48 (-/+ 7 days)
Informed consent & Registration	x									
Randomisation		x								
Rituximab / placebo			x	x			x	x		
Vital signs			x	x			x	x		
Demographics & Medical History	x[1]									
Pregnancy Test	x					x				x
Physical examination		x				x				x
Chest X-ray & ECG	x[6]									x
VAS Scales (Fatigue & Oral dryness)	x									
Unstimulated Whole Salivary flow	x				x	x			x	x
Stimulated Whole Salivary flow		x			x	x			x	x
Schirmers I test		x			x	x			x	x
Patient and Physician Questionnaires		x			x	x			x	x
Health Economics Patient & Physician Questionnaires					x	x			x	x
Local Samples										
Immunology bloods 1 (IB1)	x				x[7]	x[7]			x[7]	x[7]
Routine blood tests 1 (RB1)	x[5]				x	x			x	x
Routine blood tests 2 (RB2)				x				x		
Routine blood tests 3 (RB3)	x					x				x
Routine blood tests 4 (RB4)	x									
Bence-Jones Protein	x					x				x
Central Samples										
Immunology bloods 2 (IB2)		x[2]			x	x			x	x
Immunology bloods 3 (IB3)		x				x				x
Immunology bloods 4 (IB4)		x			x	x			x	x
Biobank sample 1 (BB1)		x								
Biobank sample 3 (BB3)		x			x	x			x	x
Safety evaluation		Monitor during study treatment and 30 days after the last dose of protocol treatment								
Labial gland biopsy (BB2[3])		x			x					x
Salivary gland ultrasound scans[3]		x			x					x

[1]Includes inclusion and exclusion criteria, medications and co-morbidity.
[2]Repeat cryoglobulins at week 24 and week 48 if abnormal result is obtained at baseline.
[3]An extra visit may be scheduled for this optional procedure (procedure only be performed in consenting patients at centres with specialist facilities).
[4]Midpoint assessments must be performed within 7 days prior to dosing at week 24.
[5]Additional tests only if clinically indicated (Coombs test, eGFR, urinary albumin-creatinine ratio, blood glucose).
[6]Chest X-ray to be performed at screening unless one is available within the previous 6 months were results were normal.
[7]IgG and C3/C4 only to be analysed locally.

Key to blood samples in the study schedule:

- Immunology Bloods 1 (IB1) = RF, IgG, IgA, IgM + EP, anti-Ro/La, C3/C4, b2microglobulin, anti-TTG screen - analysed locally
- Immunology Bloods 2 (IB2) = RF, anti-Ro/La, IgG, IgA, IgM + EP, C3/C4, ANA, dsDNA, b2microglobulin, - analysed centrally
- Immunology Bloods 3 (IB3) = Functional antibodies, HACA, BlyS/BAFF – analysed centrally
- Immunology Bloods 4 (IB4) = FACS, CD4/8 T-cell microarray - analysed centrally
- Routine Bloods 1 (RB1) = U&E, creatinine, LFTs, CRP, CPK, FBC, ESR, urine dipstick - analysed locally
- Routine Bloods 2 (RB2) = FBC, creatinine, LFTs - analysed locally
- Routine Bloods 3 (RB3) = Thyroid-stimulating hormone (TSH) - analysed locally
- Routine Bloods 4 (RB4) = Hepatitis B & C screen - analysed locally
- Biobank samples (BB1) =, PAX gene DNA - analysed centrally
- Biobank sample (BB2) = PAX gene RNA from biopsy – analysed centrally
- Biobank sample (BB3) = Serum PAX gene RNA – analysed centrally
- Bence-Jones Protein = Urine sample - analysed locally