

Written and verbal information of the trial and informed consent

Register patient (via CTRU 24 hour registration system)

Primary Sjögren's Syndrome
Fulfilling AECG Criteria
Fatigue & Dryness
If diagnosis using AECG criteria is ≥ 10 years evidence of systemic involvement is required

Full eligibility screen (within 28 days prior to start of treatment)

Randomise patient (via CTRU 24 hour randomisation system)

Baseline evaluations (within 14 days prior to start of treatment)

Physical examination; stimulated salivary flow; Schirmers I test; questionnaires;
Research blood samples to central lab (Bart's & London)
Labial gland biopsy and ultrasound imaging in a subset of patients where site facilities permit (supplementary consent for labial gland biopsy and salivary gland ultrasound scan)

Rituximab 1000mg (Day 1 & 15)
Methylprednisolone, chlorpheniramine,
paracetamol
Oral prednisolone days 2-7

Placebo infusion (Day 1 & 15)
Methylprednisolone, chlorpheniramine,
paracetamol
Oral prednisolone days 2-7

Follow-up evaluations at weeks 16 and 24.

Local investigations: Blood tests, clinical assessments, questionnaires, urine dipstick and pregnancy test.
Research blood samples to central lab (Bart's & London)
Labial gland biopsy and ultrasound imaging in a subset of patients where site facilities permit (supplementary consent for labial gland biopsy and salivary gland ultrasound scan) at circa week 16.

Rituximab 1000mg (Week 24 & 26)
Methylprednisolone, chlorpheniramine,
paracetamol
Oral prednisolone days 2-7

Placebo infusion (Week 24 & 26)
Methylprednisolone, chlorpheniramine,
paracetamol
Oral prednisolone days 2-7

Follow-up evaluations at weeks 36 and 48.

Local investigations: Blood tests, clinical assessments, questionnaires, urine dipstick and pregnancy test.
Research blood samples to central lab (Bart's & London). Chest X-ray and ECG at week 48.
Labial gland biopsy and ultrasound imaging in a subset of patients where site facilities permit (supplementary consent for labial gland biopsy and salivary gland ultrasound scan) at circa week 48.

Study completed

Patient returns to routine care