A Phase II study of Rituxmab for the treatment of Sjogrens Syndrome

ACTRN12605000396628

Status	RECRUITING
Phase	Phase 2
Sponsor	St Vincent's Hospital / University of New South Wales
Enrollment	10 participants

Plain Language Summary

This study is testing whether a medication called rituximab (Rituxan) can help treat Sjogren's syndrome. Sjogren's syndrome is an autoimmune condition where the immune system attacks moisture-producing glands, causing severe dry eyes and dry mouth. Rituximab works by reducing a certain type of immune cell. Researchers hope it may reduce symptoms and improve saliva and tear production.

You may be eligible if:
- You are a female
- You have been diagnosed with Sjogren's syndrome according to established European-American criteria
- Your condition has been stable for at least 3 months
- You are not taking aspirin or anti-inflammatory drugs (NSAIDs) within 7 days of biopsies
- You are 18 years of age or older

You may NOT be eligible if:
- Your dry mouth was caused by radiation treatment
- You have had previous salivary gland surgery
- You have a blocked salivary duct
- You are taking certain medications that affect saliva production
- You have previously received rituximab
- You have had a live vaccine within 4 weeks of treatment
- You have a history of cancer, recurring infections, or immune deficiency
- You are pregnant or breastfeeding

Talk to your doctor about whether this trial might be right for you.

Key Eligibility Criteria

Inclusion (1)

• Sjogrens Syndrome according torecently updated European-American criteria, 2. Unchanged Sjogrens Syndrome for atleast 3 months 3. no aspirin or NSAID therapy within 7 days of each parotid or labial biopsy.

Exclusion (1)

• radiation-induced xerostomia2. prior salivary gland surgery3. known parotid duct obstruction4. anticholinergic and sympath-omimetic therapy5. prior rituxmab therapylive vaccine within 4 week of therapy6. history of cancer, recurrent bacterial infections or immunodeficiency7.pregnacy or brest feeding8. lab abnormality at screening7.

Locations (1 total)

Australia