

Immunomodulatory Therapy to Restore Ovarian Function and Improve Fertility in Women With Autoimmune Premature Ovarian Insufficiency

NCT07509840

Status	RECRUITING
Phase	Phase 3
Sponsor	Angelica Lindén Hirschberg
Enrollment	40 participants

Key Eligibility Criteria

Inclusion (5)

- The subject has given their written consent to participate in the trial
- Autoimmune POI (FSH \gt 25 IU/L) including the presence of oligo/amenorrhea lasting at least 4 months, and elevated FSH levels (FSH \gt 25 IU/L) confirmed on two separate occasions, with measurements taken at least 4 weeks apart and Addison's disease or ab positivity for 21-hydroxylase or other relevant autoantibodies (SCC, 17-OH, NALP5)
- years of age
- Body mass index between 19-30
- Willing to use effective non-hormonal contraceptive (such as intra uterine device (IUD), sexual abstinence, male or female condom with or without spermicide, cap, diaphragm or sponge with spermicide) method during the 18-month study period

Exclusion (17)

- Hypersensitivity to rituximab, any of the AxMPs, or any of the excipients (as detailed in the SmPC for the various IMPs)
- Active, severe infection or JCV positivity
- Active hepatitis B infection
- Severe immunosuppression
- Severe cardiac disease
- ... and 12 more (see full listing online)

Locations (2 total)

Department of Obstetrics and Gynecology, Karolinska University Hospital, Stockholm, Sweden
Karolinska University Hospital, Stockholm, Sweden