

Hormone Replacement Therapy in Adolescents With Premature Ovarian Insufficiency

NCT06851754

Status	RECRUITING
Phase	Phase 3
Sponsor	Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)
Enrollment	185 participants

Key Eligibility Criteria

Inclusion (10)

- To be eligible to participate in this study, an individual must meet all the following criteria:
 - Individuals aged 11-19 years, inclusive, at the time of enrollment.
 - Diagnosis of premature ovarian insufficiency.
 - Documentation of two elevated serum FSH measurements, at least month apart, greater than the testing laboratory's the upper reference range (for age/Tanner stage).
 - Identify as female (i.e., sex assigned at birth)
- ... and 5 more (see full listing online)

Exclusion (8)

- Male participants are excluded from both study groups (POI and Healthy Volunteers) as POI affects only the female reproductive system, while pregnant participants are not eligible to have DXA or HRpQCT imaging for safety reasons.
 - An individual who meets any of the following criteria will be excluded from participation in this study:
 - POI in the setting of Turner syndrome.
 - Patients who screened positive for celiac disease.
 - Receipt of any medications including HRT determined by the investigator to affect bone metabolism 3 months prior to enrollment.
- ... and 3 more (see full listing online)

Locations (1 total)

National Institutes of Health Clinical Center, Bethesda, Maryland, United States