

Role of Estrogen on Skeletal Outcomes in FHA

NCT07010146

Status	RECRUITING
Phase	Phase 2
Sponsor	University of Virginia
Enrollment	150 participants

Key Eligibility Criteria

Inclusion (4)

- Females, age 14-25 years, skeletally mature with bone age \leq 14 years (only 2% of growth left)
- Women of reproductive age: use of an effective non-hormonal contraceptive method or a progestin releasing intrauterine device (no systemic skeletal effects) for study duration if sexually active
- Biochemical criteria: negative HCG (pregnancy test), normal TSH, prolactin, potassium, ALT d3 times upper limit of normal, LDL \leq 190 mg/dl
- Menstrual criteria: \leq 3 menses in the preceding 6 months.

Exclusion (8)

- Disease other than FHA known to affect bone, including untreated thyroid dysfunction, Cushing's disease, renal failure, diabetes mellitus
- Use of other medications known to affect bone metabolism within 3 months of the study (other than calcium and vitamin D supplementation)
- Substance use disorder; current smoker ($>$ 10 cigarettes per day)
- Pregnant, planning to become pregnant within 12 months of the end of treatment and/or breastfeeding
- Hypertension or use of anti-hypertensive medications
- ... and 3 more (see full listing online)

Locations (2 total)

University of Virginia Medical Center, Charlottesville, Virginia, United States
University of Virginia, Charlottesville, Virginia, United States