

Romozosumab as an Adjunct to Physiologic Estrogen Replacement in Functional Hypothalamic Amenorrhea

NCT06533865

Status	RECRUITING
Phase	Phase 3
Sponsor	Massachusetts General Hospital
Enrollment	114 participants

Key Eligibility Criteria

Inclusion (13)

- For FHA and controls:
- Female, age 14-30 years, skeletally mature with bone age \leq 12 years
- For women of reproductive age, agree to use an effective non-hormonal contraceptive method or a progestin releasing intrauterine device (no evidence of systemic skeletal effects) or implant for the study duration
- Biochemical criteria:
- Negative HCG (pregnancy test)
- ... and 8 more (see full listing online)

Exclusion (18)

- For FHA and controls
- Disease other than FHA known to affect bone, including untreated thyroid dysfunction, Cushing's disease, renal failure, diabetes mellitus
- Use of bisphosphonates
- Use of other medications known to affect bone metabolism within 3 months of the study (other than calcium and vitamin D supplementation).
- Current use of systemic corticosteroids
- ... and 13 more (see full listing online)

Locations (2 total)

Massachusetts General Hospital, Boston, Massachusetts, United States
University of Virginia Medical Center, Charlottesville, Virginia, United States