

Mechanisms of Anabolic Osteoporosis Therapy

NCT05688969

Status	RECRUITING
Phase	Not Applicable
Sponsor	Massachusetts General Hospital
Enrollment	16 participants

Key Eligibility Criteria

Inclusion (5)

- All postmenopausal women who are prescribed romosozumab by their treating physicians, meet the FDA-defined indication for romosozumab, and who are not at increased risk for a bone marrow aspirate or bone biopsy will be offered enrollment. The FDA approved indication for romosozumab is: "the treatment of osteoporosis in postmenopausal women at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy." Volunteers must be:
 - Female aged ≥ 45 years
 - Postmenopausal by either of the following criteria:
 - ≥ 36 since last spontaneous menses
 - ≥ 36 months since hysterectomy, plus serum FSH ≥ 40 units / liter if < 60 years

Exclusion (9)

- renal disease (stage 4 CKD)
- elevated blood PTH (intact PTH ≥ 77 pg/ml).
- serum 25-OH vitamin D < 20 ng/ml
- major psychiatric disease that in the opinion of the investigator would preclude the subject from providing adequate informed consent or completing the protocol procedures.
- excessive alcohol use or substance abuse that would preclude the subject from providing adequate informed consent or completing the protocol procedures.
- ... and 4 more (see full listing online)

Locations (1 total)

Mass General Brigham, Boston, Massachusetts, United States