

ROMOSUZUMAB (EVENTY[®]) FOR PREMENOPAUSAL IDIOPATHIC OSTEOPOROSIS

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About the Study

Participation

- This is a two-year treatment study
- Participants will receive Eventy[®] for one year followed by Prolia[®] for one year.
- Before you begin participation in this study, we will confirm that you have Idiopathic Osteoporosis (IOP) by reviewing your medical history, lab and imaging results.

Procedures

Over the course of the study, participants will have the following procedures to measure treatment response:

- Bone density test & vertebral fracture assessment on the densitometry machine
- High resolution CT scan of the arm & leg (HRpQCT)
- CT scan of the spine (cQCT)
- Blood & urine collection

Design

This is an open-label study of sequential Eventy[®] followed by Prolia[®] for the treatment of idiopathic osteoporosis in premenopausal women. This is not a randomized trial. All participants will receive both active treatments.

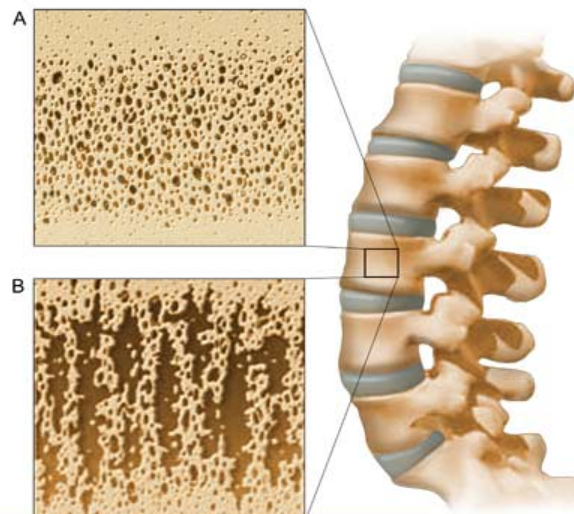
Medications

Eventy[®] (romosozumab) is a treatment that stimulates bone formation, and to a lesser extent, decreases bone breakdown. It is FDA approved for the treatment of osteoporosis in postmenopausal women.

Prolia[®] (denosumab) is a treatment that decreases bone breakdown. It is FDA approved for the treatment of osteoporosis in men and postmenopausal women, and adults with glucocorticoid-induced osteoporosis.

What is idiopathic osteoporosis (IOP)?

While low bone density and low trauma fractures commonly affect postmenopausal women, they may rarely occur in young and healthy women. When osteoporotic fractures occur in a premenopausal woman without a known cause, this is known as Idiopathic Osteoporosis (IOP).



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A) Healthy bone density B) Osteoporosis

You may be eligible if:

- You are between the ages of 18 and 45
- You are a premenopausal woman with regular menstrual periods
- You have unexplained premenopausal osteoporosis
- You have had a fracture that is considered to be low trauma

You will not be eligible if you have:

- Hyperparathyroidism
- Cancer
- Liver or Kidney Disease
- Inflammatory Bowel Disease
- Currently use glucocorticoids or blood-thinners
- Are currently pregnant or breastfeeding

Please contact us for additional information.

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Columbia University IRB

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