

A Comparative Study to Valuating the Efficacy and Safety of QL1206 and Prolia®

NCT07062978

Status	RECRUITING
Phase	Phase 3
Sponsor	Qilu Pharmaceutical Co., Ltd.
Enrollment	278 participants

Key Eligibility Criteria

Inclusion (5)

- Subjects who agree to participate in the study and sign the informed consent form.
- Postmenopausal women who can walk freely, aged 50-85 years (including 50 and 85 years old).
- Subjects whose absolute value of bone mineral density (BMD) in the lumbar or total hip area meets T values ≤ -2.5 and ≥ -4.0 .
- Subjects who must have at least one of the following risk factors: History of previous fragility fractures (occurring after the age of 40); history of hip fractures in fathers or mothers; increased bone turnover rate during screening; low body weight (BMI ≤ 19 kg/m²); advanced age (aged ≥ 65 years); current smoke.
- The duration of spontaneous amenorrhea was ≥ 2 years or ≥ 2 years after bilateral oophorectomy. If the status of bilateral oophorectomy is unknown or if the ovaries are preserved after hysterectomy, follicle stimulating hormone (FSH) levels ≥ 40 mIU/mL may be used to confirm the status of postoperative menopause.

Exclusion (14)

- Bone/metabolic disease.
- Hyperparathyroidism or hypoparathyroidism.
- Thyroid condition: Hyperthyroidism or hypothyroidism.
- Rheumatoid arthritis.
- Malabsorption syndrome.

... and 9 more (see full listing online)

Locations (1 total)

Zhejiang Provincial People's Hospital Bijie Hospital, Guizhou, China