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APPENDIX

Eligibility Criteria

Inclusion Criteria

- Adult women or men, aged ≥55 to ≤95 years at randomization
- Acute unilateral low-energy intertrochanteric or femoral neck fracture as the primary injury, confirmed by x-ray and amenable to repair by internal fixation
- Intertrochanteric fractures must have had ≥2 displaced fragments
- Internal fixation of the fracture with devices approved by local regulatory agency, performed no later than 7 days after injury for intertrochanteric or undisplaced femoral neck fractures and no later than 2 days after injury for displaced femoral neck fractures
    - Intertrochanteric fracture: sliding hip screw or intramedullary nail
    - Femoral neck fracture: sliding hip screw or at least 3 cancellous screws
- Pre- and postoperative care performed as defined below:
    - Antibiotic prophylaxis
    - Deep vein thrombosis prophylaxis (systemic and/or mechanical, including early ambulation)
    - Osteoporosis assessment per local standard-of-care guidelines
    - Surgical repair with a device that has been approved by a local regulatory agency; for sliding hip screws, minimum 3 holes in side plate
    - Encouraged postoperative ambulation and weight-bearing per local standards
    - In-hospital assessment by trained physical therapist (range of motion, gait training, training for ambulation with assistive device) followed by:
        - Instructions for home-based self-rehabilitation
        - Supervised outpatient rehabilitation program
        - Admission into rehabilitation hospital
- Informed consent provided by the patient or patient's legally acceptable representative

Exclusion Criteria

- Conditions that may affect the ability to perform functional or clinical assessments, such as:
    - Severe symptomatic osteoarthritis of the lower extremity
    - Inability to independently rise from armchair or walk 200 meters before hip fracture (use of unilateral assistive device or rolling walker is acceptable)
    - Cognitive deficit, as defined by Mini-Mental Status Examination score <22 at the time of randomization
    - Symptomatic neurological conditions such as Parkinson's disease or persistent gross motor or sensory deficits, such as hemiparesis or hemiplegia

  - Presence of concomitant injuries, such as rib fractures, wrist fractures, or acute symptomatic vertebral fractures that would severely impair the ability to rise from a chair
  - Associated extremity injuries, including ipsilateral or contralateral fractures of the foot, tibia or fibula, wrist, humerus, femoral shaft, femoral head, or hip dislocation that may delay weight-bearing beyond 1 week after surgery

- Use of bone grafts or bone substitutes at the time of fracture fixation
- Head injury as defined by Glasgow Coma Scale <13 prior to randomization
- Major polytrauma or significant axial trauma, with Injury Severity Score >16
- Pathological fracture or history of metabolic or bone disease (except osteoporosis) that may have interfered with the interpretation of the results, such as Paget's disease, rheumatoid arthritis, osteomalacia, osteopetrosis, ankylosing spondylitis, Cushing's disease, hyperprolactinemia
- History of symptomatic spinal stenosis that had not been surgically corrected. If surgically corrected, the patient must have been asymptomatic to be eligible for the study
- History of facial nerve paralysis
- Malignancy (except fully resected cutaneous basal cell or squamous cell carcinoma, cervical carcinoma in situ) within the last 5 years
- Severe asthma or severe chronic obstructive pulmonary disease or recent exacerbation
- Myocardial infarction or unstable angina pectoris within the last 12 months
- Current alcohol dependence
- History of solid organ or bone marrow transplants
- Evidence of current abnormal values for the following
  - Elevated transaminases (serum aspartate aminotransferase or serum alanine aminotransferase ≥2.0 x upper limits of normal)
  - Significantly impaired renal function as determined by creatinine clearance of ≤30 mL/min
  - Hypocalcemia or hypercalcemia, outside of 1.1 x the normal range set by the local laboratory
- Tested positive for human immunodeficiency virus, hepatitis C virus, or hepatitis B surface antigen
- Use of the following agents affecting bone metabolism
  - Within the past 12 months: parathyroid hormone, strontium, fluoride (for osteoporosis)
  - Within the past 6 months: intravenous bisphosphonates, denosumab, odanacatib
  - Within the past 3 months: calcitonin, tibolone, cinacalcet, systemic glucocorticosteroids (≥5 mg prednisone equivalent per day for more than 10 days)
- Bone morphogenetic protein (BMP)-2 or BMP-7 at the time of definitive fracture fixation
- Currently enrolled in another investigational device, drug, or biologics product study, or <30 days since ending another investigational device, drug, or biologics product study(ies), or receiving other investigational agent(s)
- Previous enrollment in a romosozumab clinical study

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- Women of childbearing potential: patient refused to use an effective contraception (or true abstinence) during treatment with study product and for an additional 3 months after the end of treatment with study product
- Patient was pregnant (eg, positive human chorionic gonadotropin test) or breast-feeding, or planned to become pregnant during treatment with study product or within 3 months after the end of treatment with study product
- Known sensitivity or intolerance to any of the products to be administered as part of the study
- Not available for protocol-required study visits
- Any disorder that may have compromised the ability of the patient to give written informed consent and/or to comply with all required study procedures
- Any condition or illness (acute, chronic, or history) that may have interfered with the evaluation of the safety of the study product or may otherwise compromise the safety of the patient

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TABLE Randomized Patients by Country

Country	Number of Trial Sites	Enrollment N = 332 n (%)
Argentina	2	24 (7.2)
Australia	1	3 (0.9)
Belgium	4	25 (7.5)
Bulgaria	1	2 (0.6)
Canada	4	32 (9.6)
Denmark	4	34 (10.2)
Estonia	1	1 (0.3)
Finland	3	8 (2.4)
Germany	2	4 (1.2)
Greece	5	60 (18.1)
Hong Kong	1	4 (1.2)
Hungary	4	14 (4.2)
India	9	45 (13.6)
Italy	3	6 (1.8)
Latvia	2	24 (7.2)
Lithuania	2	5 (1.5)
Netherlands	3	9 (2.7)
New Zealand	1	3 (0.9)
Poland	3	9 (2.7)
Switzerland	2	2 (0.6)

United Kingdom	2	13 (3.9)
United States	4	5 (1.5)