Investigating the effect of Romosozumab on osteoporosis following spinal cord injury

ACTRN12623000141640

Status	RECRUITING
Phase	Phase 4
Sponsor	Princess Alexandra Hospital, Metro South Health
Enrollment	32 participants

Plain Language Summary

Spinal cord injury (SCI) causes rapid and severe bone loss below the level of the injury, often leading to osteoporosis and an increased risk of fractures from minor knocks or falls. Currently, there are no highly effective treatments for this type of bone loss. This study is testing whether a drug called romosozumab — which works by blocking a protein called sclerostin that normally limits bone formation — can prevent the dramatic bone loss that follows SCI.

Participants will be randomly assigned to receive either romosozumab injections for 12 months followed by a bone-strengthening infusion (zoledronic acid), or zoledronic acid alone. Bone density will be measured at regular intervals to compare how well each approach protects bone. The goal is to start treatment early, within 3 months of the injury, when bone loss is fastest.

You may be eligible if you are aged 18 to 65, have had a spinal cord injury within the past 3 months, have a significant (complete or near-complete) SCI, and are able to consent to participate. People with previous bone disease, vitamin D deficiency, significant kidney disease, or certain hormonal disorders are not eligible.

Key Eligibility Criteria

Inclusion (4)

- Adults aged 18 years to 65 years (upper age limit is to reduce the influence of age on ability of the skeleton to respond to pharmacologic stimulation and reduce the risk of losing participants to follow-up)
- Within 3 months of acute SCI
- American Spinal Injury Association (ASIA) Impairment Scale A-C
- People with SCI and traumatic brain injury will be included if they are able to provide informed consent

Exclusion (9)

- Unable or unwilling to provide informed consent (consent not granted by substitute decision maker) or comply with follow-up and study protocol.
- History of prior bone disease (i.e., Paget’s disease, primary hyperparathyroidism, current or previously treated osteoporosis)
- Documented heterotopic ossification (HO)
- Endocrinopathies (including untreated hyperthyroidism, active Cushing’s Syndrome, hypocalcaemia)
- Chronic kidney disease (glomerular filtration rate 20%

... and 4 more (see full listing online)

Locations (1 total)

Princess Alexandra Hospital - Woolloongabba, QLD, Australia