Preventing Osteoporosis in Patients with Spinal Cord Injury (SCI)

ACTRN12618000915257

Status	RECRUITING
Phase	Phase 3
Sponsor	Northern Sydney Local Health District - Royal North Shore Hospital
Enrollment	100 participants

Plain Language Summary

After a spinal cord injury, bones — particularly in the pelvis and legs — rapidly lose density in the weeks and months that follow. This happens because the muscles that normally stress and stimulate bone through movement are no longer active. The resulting osteoporosis can lead to fractures from minor bumps or falls, which in turn cause serious complications and can even be life-threatening.

This study aims to prevent this bone loss by treating patients early — within 8 to 12 weeks of an acute traumatic spinal cord injury — with zoledronic acid, a medication that is already approved and widely used to treat osteoporosis in other settings. Researchers hope that starting treatment early enough can preserve bone density and reduce the risk of fractures down the track.

You may be eligible if you are 18 or older and have recently experienced a traumatic spinal cord injury. People with non-traumatic causes of spinal cord injury (such as tumours or degenerative disease), known sensitivity to zoledronic acid, pregnancy, or active malignancy in the past five years are not eligible.

Key Eligibility Criteria

Inclusion (2)

- Adults aged 18 years and older who have sustained an acute traumatic spinal cord injury.
- Subject has provided an informed consent.

Exclusion (7)

- Subjects with a non-traumatic spinal cord injury (eg tumours, degenerative diseases of the spinal column, vascular and autoimmune disorders)
- Subject is currently involved in another investigational device or drug study, or <30 days since ending another investigational device of drug study or receiving an investigational agent.
- Malignancy within the past 5 years, except for non-melanoma skin cancers, cervical or breast ductal carcinoma in situ.
- Subjects with a known sensitivity to any of the drugs to be administered (zoledronic acid, vitamin D if required).
- Subject is known to have any condition or illness (acute, chronic or history) which, in the opinion of the investigator, might interfere with the evaluation of the study treatment or may otherwise compromise the safety of the patient

... and 2 more (see full listing online)

Locations (1 total)

Royal North Shore Hospital - St Leonards, NSW, Australia