

The Conceal Trial - Targeted Muscle Re-innervation (TMR) in the treatment of chronic neuropathic and phantom limb pain following a major lower limb amputation; a functional brain MRI study

ACTRN12622000796785

Status	RECRUITING
Sponsor	Monash Health
Enrollment	80 participants

Plain Language Summary

After a lower limb amputation, many people experience phantom limb pain — an often severe, distressing sensation of pain in the limb that is no longer there. It can be incredibly difficult to treat, and medications frequently provide only partial relief. Targeted Muscle Re-innervation (TMR) is a surgical technique where the nerves from the amputated limb are redirected into nearby muscles, which may reduce or eliminate the signals causing phantom pain.

The CONCEAL trial is testing whether TMR is more effective than continuing medication-based pain management for chronic phantom limb and neuropathic pain in lower limb amputees. Participants are randomly assigned to either TMR surgery or medical management in a 2:1 ratio. Brain MRI scans are performed before and 12 months after treatment to understand what changes in the brain's pain processing areas. Pain and function questionnaires are completed at multiple points over 12 months.

You may be eligible if you had a major lower limb amputation within the past 5 years, currently have chronic neuropathic or phantom limb pain, and have not previously had any surgical treatment for this pain. People with double amputations, previous TMR surgery, cognitive impairment, or inability to have an MRI are excluded. The study is led by Monash Health.

Key Eligibility Criteria

Inclusion (1)

- Patients who have undergone a major lower limb amputation in the last 5 years and currently diagnosed with chronic neuropathic and phantom limb pain, but who have not undergone previous surgical intervention to treat their neuropathic and phantom limb pain

Exclusion (4)

- Patients who are double amputees
- Patients who have already undergone TMR
- Patients unable to proceed with a functional brain MRI for any reason
- Patients with cognitive impairment

Locations (1 total)

Monash Medical Centre - Clayton campus - Clayton, VIC, Australia

<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12622000796785>

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