Ultra Low Frequency Neuromodulation for Nociceptive Chronic Low Back Pain

NCT06763653

Status	RECRUITING
Phase	Not Applicable
Sponsor	Presidio Medical, Inc
Enrollment	303 participants

Key Eligibility Criteria

Inclusion (11)

- Chronic, intractable nociceptive axial low back pain with or without leg pain (VAS e6 cm for back pain over 7 days) for a minimum of 3 months.
- Symptoms have failed to respond adequately to conservative therapies, including: physical therapy/exercise, medications, and interventional therapies.
- Back pain greater than leg pain.
- ODI score e30 and d80.
- On stable pain medications or on no pain medications.

... and 6 more (see full listing online)

Exclusion (13)

- Have a systemic condition or disease not stabilized or judged by the investigator to be incompatible with participation in the study.
- Suffer from severe cognitive impairment that would impair ability to complete subject questionnaires or operation of the device.
- Diagnosed with an active disruptive psychological or psychiatric disorder or other known condition significant enough to impact perception of pain, compliance, intervention and/or ability to evaluate treatment outcome as assessed by a clinical psychologist or psychiatrist.
- Presence of spinal stenosis, structural spinal abnormality, or spinal instrumentation observed on MRI or CT that would make lead placement unsafe or untowardly difficult.
- Previous experience with neuromodulation devices for pain.

... and 8 more (see full listing online)

Locations (3 total)

The International Spine Centre, Norwood, South Australia, Australia
CerCare Pty Ltd, Wayville, South Australia, Australia
Monash House Research Centre, Clayton, Victoria, Australia