A study investigating movement, pain and activity in failed back surgery patients undergoing spinal cord stimulation.

ACTRN12615001038583

Status	RECRUITING
Sponsor	Dr Richard Sullivan
Enrollment	25 participants

Plain Language Summary

This study looks at how spinal cord stimulation (SCS) — a treatment where a small device delivers mild electrical pulses to the spinal cord — affects pain, movement, and daily activity in people with ongoing back and leg pain after previous back surgery (called failed back surgery syndrome). Researchers will use sensors to objectively measure how much people move before and after the device is implanted.

You may be eligible if:
- You are 18 years old or older (male or female)
- You have persistent back and leg pain for at least 6 months after one or more back surgeries
- Your doctor has recommended a trial of spinal cord stimulation
- Your average pain is at least 3 out of 10
- Your disability score (Oswestry) is above 20%

You may NOT be eligible if:
- You have had back surgery in the past 6 months
- You already have a spinal cord stimulator, other implanted nerve stimulator, or intrathecal pump
- You are pregnant or planning to become pregnant
- You have a severe hearing impairment or cannot follow verbal instructions in English
- You have another medical or psychological condition that would interfere with the study

Talk to your doctor about whether this trial might be right for you.

Key Eligibility Criteria

Inclusion (7)

- Males and Females aged over 18
- FBSS, defined as persistent or re-current low back and leg pain of at least 6 months duration, following at least one decompression and/or fusion procedure
- Deemed as clinically appropriate for a trial of spinal cord stimulation for the treatment of FBSS
- Minimum average pain level measured on a numerical rating scale of at least 3
- Activity limitation as recorded by the Oswestry disability index of > 20%

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

Exclusion (10)

- Lower back surgery within previous six months.
- The subject is being currently treated or has been treated with SCS, subcutaneous or peripheral nerve stimulation, intrathecal drug delivery system, or is awaiting further lumbar surgery.
- Is pregnant or planning to become pregnant during the course of the study;
- Subjects with a severe hearing impairment or inability to follow verbal instructions.
- Evidence of non-mechanical contributing cause for lower back pain e.g. neoplasm, infection, fracture, inflammatory disorder or persistent non-fluctuating pain.

... and 5 more (see full listing online)

Locations (1 total)

VIC, Australia