

# To evaluate the effectiveness of two (2) different waveforms of Spinal Cord Stimulation in a population of patients with back and leg pain due to failed back surgery syndrome

ACTRN12618000721202

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Status	RECRUITING
Sponsor	Vincent Galan, MD
Enrollment	20 participants

## Plain Language Summary

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Spinal cord stimulation (SCS) is an established treatment for chronic back and leg pain, particularly in people who have had back surgery that didn't fully relieve their pain — a condition called "failed back surgery syndrome." It works by delivering gentle electrical pulses to the spinal cord through implanted leads, interrupting pain signals before they reach the brain. Two different electrical patterns are currently available: High Density stimulation and BURST stimulation, both of which have been shown to reduce pain, but they haven't been directly compared head-to-head.

This study is running a direct comparison of the two approaches in people who are candidates for SCS, to find out which one works better for managing chronic back and leg pain. Participants will try both patterns and the results will be measured objectively.

You may be eligible if you are 18 or older, have chronic back and leg pain rated at least 5 out of 10 on a pain scale, are a candidate for spinal cord stimulation, and are willing to attend study visits and not increase your pain medications during the trial period. People who have previously had an SCS device or similar implant, or who have significant unresolved psychological or legal issues related to their pain, may not be eligible. This could be an opportunity to access SCS therapy while contributing to evidence about which approach works best.

## Key Eligibility Criteria

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### Inclusion (8)

- Candidate for SCS system (trial and implant) per labeled indication (back and leg pain)
- Baseline diary-reported average NPRS is equal or greater than 5 for both trunk and limbs pain.
- Willing and able to provide a signed and dated informed consent
- At least 18 years old at the time of informed consent
- Willing and able to attend visits and comply with the study protocol
- ... and 3 more (see full listing online)

### Exclusion (4)

- Currently enrolled in or plans to enroll in any concurrent drug and/or device study that may confound study results.
- Based on the medical opinion of the Principal Investigator, Sub- Investigator, Psychologist and/or Psychiatrist, the subject has other psychological conditions (e.g., psychosis, suicidal ideation, borderline personality disorder, somatization, narcissism), or other health conditions (e.g., substance abuse, another chronic condition requiring the regular use of significant pain medications) that would preclude his/her enrollment in the study or potentially confound the results of the study
- Tried or implanted with SCS, subcutaneous stimulation, peripheral nerve stimulation or an implantable intrathecal drug delivery system which utilizes tonic (paresthesia) stimulation.
- Unresolved major issues of secondary gain (e.g., social, financial, legal), as determined by the investigator

## Locations (1 total)

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<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12618000721202>  
GEORGINA, United States of America

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