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Comparison of spinal cord stimulation in combination with standard pain treatment versus standard pain treatment only in patients with intractable chronic back pain without previous history of spine surgery

Submission date
15/06/2020

Recruitment status
No longer recruiting

Registration date
29/06/2020

Overall study status
Completed

Last Edited
23/04/2025

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims

It is estimated that about 20% of the population worldwide is affected by moderate to severe chronic pain. Chronic pain becomes a burden to the individual as this affects a person's ability to carry out many daily life activities, such as exercising, walking, driving a car, attending social events, or performing household chores. Chronic pain is considered one of the most pervasive and intractable conditions affecting at least one-third of the population at an estimated cost of five hundred billion dollars per year, when combining health-related expenditure and the cost-impact on loss of productivity and income.

Conventional medical management (CMM), including medication and physical therapy, is often not adequate for treating chronic pain. Medication therapy based on opioids may also lead to addiction. When these treatments fail to provide pain relief, imaging is performed to assess candidacy for back surgery. However, surgery is only indicated for those patients with mechanical instability or pinched nerves. For the many patients for whom imaging does not clearly show a cause of chronic back pain, or for the patients that have other medical issues preventing an invasive surgical procedure, there are few alternative treatment options. Furthermore, surgical interventions have also failed to resolve severe cases of neuropathic pain and intractable back pain for many patients.

Spinal cord stimulation (SCS) is a proven therapy that has been in use for about 50 years for various types of chronic pain. SCS is a reversible therapy that allows patients to evaluate the therapy for several days using an external neurostimulator before receiving an implantable neurostimulator (INS) system. SCS involves the surgical placement of two leads (which look like very thin wires) into a small area near the spinal cord. Electrical stimulation is delivered through these wires by a small, battery-operated, rechargeable SCS implanted generator. There is good evidence to recommend SCS in people with back pain without a history of spinal surgery, particularly because SCS is a less invasive and reversible therapy that may provide greater long-term benefits than more invasive surgical approaches.

This study will evaluate SCS programming with conventional medical management in comparison to conventional medical management alone for chronic back pain sufferers with or without leg pain and who are not considered candidates for spine surgery.

Who can participate?
Adults aged 18 and older who have chronic back pain

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive SCS. Those in the second group receive medical pain management as per the Center's usual practice. SCS involves the surgical placement of two leads (which look like very thin wires) into a small area near the spinal cord. Electrical stimulation is delivered through these wires by a small, battery-operated, rechargeable SCS implanted generator. Each participant is followed for 24 months. The participants attend regular clinic visits to complete questionnaires and to provide feedback on their pain.

What are the possible benefits and risks of participating?
Participants may benefit from both treatments (SCS and conventional medical management) to relieve their pain. There are no direct risks of taking part in this study, although the general risks of having a spinal stimulation device in place apply.

Where is the study run from?
1. Hospital Clínico Universitario de Valencia (Spain)
2. AZ Delta Roeselare (Belgium)

When is the study starting and how long is it expected to run for?
January 2020 to March 2024

Who is funding the study?
SGX International LLC (USA)

Who is the main contact?
Ms Thanh Tran, thanh.tran2@medtronic.com

Contact information

Type(s)
Scientific

Contact name
Ms Thanh Tran

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT06442410

Protocol serial number
DTM-INT-2020PM2

Study information

Scientific Title
Comparison of differential target multiplexed spinal cord stimulation therapy combined with conventional medical management to conventional medical management alone in the treatment of intractable back pain subjects without previous history of lumbar spine surgery

Acronym
EU RCT DTM SCS vs CMM

Study objectives
This study is being conducted to document the safety, clinical effectiveness and health economics of Differential Target Multiplexed (DTM) Spinal Cord Stimulation (SCS) delivered through the Intellis neurostimulator (Medtronic, Minneapolis, MN, USA) in subjects with chronic back pain who are not considered candidates for spine surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 10/06/2020, Commission Medical Ethics AZ Delta (ZIekenhuis Roeselare-Menen, Deltalaan 1, 8800 Roeselare, Belgium; +32 (0)56 52 22 31; mec.mail@azdelta.be), ref: B1172020000014

Primary study design
Interventional

Study design
Multi-centre prospective randomised study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic back pain without previous history of lumbar spine surgery

Interventions
Participants are randomly allocated in a 1:1 ratio to either the control or the intervention group.

Those in the intervention group receive the DTM SCS therapy. SCS involves the surgical placement of two leads (which look like very thin wires) into a small area near the spinal cord. Electrical stimulation is delivered through these wires by a small, battery-operated, rechargeable SCS implanted generator.

The control group received the Conventional Medical Management (CMM). CMM is the standard treatment provided for chronic back pain patients if not treated with a spinal cord stimulation system – Active Comparator is DTM SCS + CMM, the device which will be used is the Intellis neurostimulator (Medtronic, Minneapolis, MN, USA).

Each participant is followed for 24 months. The participants attend regular clinic visits to complete questionnaires, and to provide feedback on their pain. The treatment for both groups is expected to last a total of 24 months.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Intellis neurostimulator (Medtronic, USA) using DTM SCS

Primary outcome(s)
Individual responder rate measured using the visual analog scale (VAS) (as defined by at least a 50% reduction in pain) at 6 months

Key secondary outcome(s)
1. Successful back pain relief measured using the visual analog scale (VAS) at 1, 3, 6, 9, 12, 18 and 24 months
2. Percentage of patients who experience at least 50% reduction in pain intensity measured using the VAS at 1, 3, 6, 9, 12, 18 and 24 months
3. Back pain intensity measured using VAS at baseline, 1, 3, 6, 9, 12, 18 and 24 months

Removed 27/01/2022 (these were incorrectly listed as secondary outcome measures. In the protocol they are indicated as additional measures):
4. Disability measured using Oswestry Disability Index (ODI) questionnaire at 3, 6, 9, 12, 18 and 24 months
5. Quality of life measured using EQ-5D & SF-12 questionnaire at 3, 6, 12, 18 and 24 months
6. Health economic outcomes measured using clinic visits, incidence of adverse events, EQ-5D, SF-12 at 1, 3, 6, 9, 12, 18 and 24 months

Completion date
17/10/2023

Eligibility

Key inclusion criteria
1. Be a candidate for SCS system (trial and implant)
2. Have been diagnosed with chronic, refractory axial low back pain with or without lower limb pain with a neuropathic component as assessed by the investigator, and are not eligible for spine surgery (e.g., lumbar fusion, discectomy, laminectomy, laminotomy) at the time of enrollment
3. Has an average back pain intensity ≥ 6.0 cm on the 10.0 cm Visual Analog Scale (VAS) at the time of enrollment

4. Be willing and capable of giving written informed consent to participate in this clinical study based on voluntary agreement after a thorough explanation of the subject's participation has been provided
5. Be willing and capable of subjective evaluation, read and understand written questionnaires, and read, understand and sign the written informed consent
6. Be 18 years of age or older at the time of enrollment
7. Be on a stable pain medication regimen, as determined by the study investigator, for at least 30 days prior to enrolling in this study
8. Be willing and able to comply with study-related requirements, procedures, and visits

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
115

Key exclusion criteria
1. Had previous lumbar spinal surgery (e.g., lumbar fusion, discectomy, laminectomy, laminotomy)
2. Has a medical, anatomical, and/or psychosocial condition that is contraindicated for commercially available IntellisTM SCS systems as determined by the Investigator
3. Has a diagnosed back condition with inflammatory causes of back pain (e.g., onset of severe pain with activity), serious spinal pathology and/or neurological disorders as determined by the investigator
4. Be concurrently participating in another clinical study
5. Has an existing active implanted device such as a pacemaker, another SCS unit, peripheral nerve stimulator, and/or drug delivery pump, etc.
6. Has a pain in other area(s) and/or medical condition requiring the regular use of significant pain medications that could interfere with accurate pain reporting, and/or confound evaluation of study endpoints, as determined by the Investigator
7. Has mechanical spine instability as determined by the Investigator
8. Has undergone, within 30 days prior to enrollment, an interventional procedure to treat back and/or leg pain, which is providing significant pain relief
9. Has unresolved major issues of secondary gain (e.g., social, financial, legal), as determined by the investigator
10. Be involved in an injury claim under current litigation or has a pending or approved worker's compensation claim

11. Be pregnant (determined by urine testing unless female subject is surgically sterile or post-menopausal. If female, sexually active, and childbearing age, subject must be willing to use a reliable form of birth control)

Date of first enrolment
01/08/2020

Date of final enrolment
27/10/2021

Locations

Countries of recruitment
Belgium

Germany

Netherlands

Spain

Study participating centre
Hospital Clínico Universitario de Valencia
Avenida Blasco Ibáñez, número 17
Valencia
Spain
46010

Study participating centre
AZ Delta
Deltalaan 1
Roeselare
Belgium
8800

Study participating centre
AZ Nikolaas
Sint-Niklaas
Belgium
-

Study participating centre

GZA - Sint Augustinus Ziekenhuis
Wilrijk
Belgium
-

Study participating centre
Universitätsklinikum Düsseldorf
Düsseldorf
Germany
-

Study participating centre
München Klinik Bogenhausen
München
Germany
-

Study participating centre
Rijnstate - Locatie Elst
Elst
Netherlands
-

Study participating centre
Maastricht University Medical Center
Maastricht
Netherlands
-

Study participating centre
Diakonessenhuis Locatie Zeist
Zeist
Netherlands
-

Study participating centre

Hospital Clínico Universitario de Santiago
A Coruña
Spain
-

Study participating centre
Hospital Universitario Puerta de Hierro Majadahonda
Majadahonda
Spain
-

Study participating centre
Hospital Universitario Virgen del Rocío
Sevilla
Spain
-

Sponsor information

Organisation
SGX International LLC

Funder(s)

Funder type
Industry

Funder Name
SGX International LLC

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		28/06/2024	21/10/2024	Yes	No
Protocol file	Clinical Investigation Plan	21/08/2020	23/04/2025	No	No
Statistical Analysis Plan	version 3.0	05/05/2022	23/04/2025	No	No