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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

### Contact details
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# Additional identifiers

### Clinical Trials Information System (CTIS)
Nil known

### 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

### Study design
Multi-centre prospective randomised study

### Primary study design
Interventional

### 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 |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |
| 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 |