# Comparison of DTM SCS Therapy Combined with standard pain treatment to standard pain treatment alone in the Treatment of Intractable Back Pain Subjects without previous history of Lumbar Spine Surgery

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The purpose of this study is to evaluate and document the safety information, how effective and cost effective the DTM SCS stimulation system is and the standard pain treatment in patients with chronic, difficult to treat back pain who are not...

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|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Other condition |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON54983

**Source**
ToetsingOnline

**Brief title**
DTM-INT 2020PM2

### Condition

- Other condition
- Spinal cord and nerve root disorders

**Synonym**
chronic, intractable back pain without history of back surgery.

**Health condition**

neuropathic, refractory chronic back pain

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** SGX International LLC (SGX Health Europe)
**Source(s) of monetary or material Support:** SGX International LLC

## Intervention

**Keyword:** Back Pain without history of back surgery, Conventional Medical Management, DTM SCS Therapy

## Outcome measures

**Primary outcome**

Percentage of randomized subjects who respond (a decrease in back pain VAS by

at least 50% compared to baseline) to SCS therapy at 6 months (superiority

analysis).

**Secondary outcome**

The secondary objectives of this study are to further demonstrate the

effectiveness of the DTM-SCS when compared to CMM for the treatment of chronic

pain of the trunk and limbs. This study will also include the characterization

of the safety & health economic analytics of DTM-SCS.

Secondary outcome measures will be assessment at 1, 3, 6, 9, 12 and 24 month

based on:

- Pain - Visual Analogue Scale (VAS)

- Disability - Oswestry Disability Index (ODI)

- Quality of Life - European Quality of Life-5 Dimensions (EQ-5D-5L)

- Patient's and clinician's global impression of change (PGIC)

- Subject satisfaction questionnaire

- Mental and Physical funcitonality - Health and Well-being questionnaire

(SF-12)

- Feedback paresthesia

- Medication use - medication log

- Work status - work status log

- Safety - incidence adverse events (AEs)

# Study description

**Background summary**

It is estimated that about 20% percent 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. In the United States, 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. Indeed, extensive use of opioid medications in the United States has led to the declaration of an epidemic crisis. 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 confounding medical issues precluding an invasive surgical procedure, there are few alternative treatment options. Furthermore, surgical interventions have also failed to remediate severe cases of neuropathies 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 (ENS) prior to receiving an implantable neurostimulator (INS) system.
SCS utilizes pulsed electric fields that are applied to the dorsal section of the spinal cord via electrode arrays, called leads, implanted in the epidural space.
The Differential Target Multiplexed SCS (DTM SCS) programming approach relies on stimulation parameters that will be set to levels that provide pain relief yet well below the levels that could cause uncomfortable paresthesia, which may result in significant pain relief from back and leg pain symptoms. This can be done with programming parameters that are currently available on the IntellisTM neurostimulator device (Medtronic, MN, USA).
In a given program group, DTM SCS will provide programs with different pulse rates and pulse widths for the goal of better pain relief. The lower stimulation amplitudes used in the DTM SCS programming approach could result in patients experiencing less uncomfortable stimulation than with a Conventional SCS programming approach. This is possible because a DTM SCS program group contains programs that allow subjects to access amplitudes below those that could cause uncomfortable paresthesia and make more adjustments to the amplitude.
There is an ongoing post-market, open-label, prospective, randomized controlled study (NCT03606187) evaluating the DTM SCS programming approach versus the Conventional one. The study includes more than 100 subjects randomized in 12 sites in the U.S. At the 3-month primary endpoint, the responder rate (percentage of subjects with >=50% pain relief) for DTM SCS programming was 80% vs 51% for the active control arm. Thus, the study met the primary objective for non-inferiority. A secondary objective of superiority of DTM SCS was also met for the primary outcome. In addition, the mean percent of back pain relief relative compared to baseline at the 3-months follow up for DTM SCS was 74% vs. 46% for conventional programming.
Thus, the ongoing study has shown that DTM SCS is more effective than conventional SCS at the 3-month primary endpoint of the study. Results also show that DTM SCS shows a risk profile in line with that of the widely documented profile for conventional SCS. Therefore, DTM SCS programming approach offers an alternative programming approach to SCS that might help thousands of chronic pain sufferers make substantial improvements in pain relief, reduction in disabilities, and reduce the likelihood of uncomfortable paresthesia.
The current study is a post-market, open-label, prospective, randomized, controlled multi-center study that will evaluate DTM SCS programming with CMM in comparison to CMM alone for chronic back pain sufferers with or without leg pain. This scientifically sound study will provide more information on safety, efficacy and health economic analytics for the DTM SCS programming approach.

**Study objective**

The purpose of this study is to evaluate and document the safety information, how effective and cost effective the DTM SCS stimulation system is and the standard pain treatment in patients with chronic, difficult to treat back pain who are not considered to be suitable for spine surgery.

**Study design**

This is a post-market, open-label, prospective, randomized, controlled, multi-center study comparing DTMTM SCS programming approach, delivered through the CE marked IntellisTM neurostimulator, to Conventional Medical Management (CMM).

Subjects meeting study entrance criteria will be randomized in a 1:1 ratio to one of two study treatment groups:
• Test treatment group with DTMTM SCS programming approach with CMM
• Control treatment group with CMM alone

Data at follow-up visits will be compared between the two treatment groups, and compared to baseline assessments collected at the beginning of the study.

There is an optional two-way crossover to the other treatment group available for all subjects who remain in the study at the 6-months visit (certain conditions to be fullfilled).

**Study burden and risks**

1. Side effects of the study medical device
The DTM spinal cord stimulation programming approach will be used with the commercially available and approved IntellisTM spinal cord stimulation system. The risks associated with spinal cord systems in general, are well characterized in the system manuals for medical users and scientific journals and are minimal compared to the side effects associated with most surgical procedures or the use of many drugs used to treat chronic pain conditions.

The site effects associated with implanting the IntellisTM system are the same as if the subject would not participate in the study. These possible site effects and the possible side effects for the pain treatment in the control group will be discussed with the study doctor.

The most common reported problems after neurostimulator implantation include : infections, displacement of the leads, pain at the implant site, loss of stimulation, and stimulation that does not meet expectations.

Additionally, the treatment is reversible and the device may be turned off and/or removed at any time for any reason. The expected risks are minimal. At each of the follow up visits, the subject's pain condition will be reviewed and

the therapy will be adjusted accordingly, if necessary.
The investigators are experienced in the diagnosis and treatment of chronic pain, have proper surgical and clinical training and will take adequate steps to ensure the subject's safety during implant procedures and throughout the study. The investigators and study personnel participating in this study are familiar with the elements of the system and their functions. However, unanticipated risks may occur.
If during the study, new information becomes availble that could influence the subject's decision about his/her participation, the study doctor will inform the subject as soon as possible without any consequenses for the treatment.

2. Pregnancy
Women who are pregnant cannot participate in this study. Also, woman should not become pregnant during the study. The spinal cord stimulator can affect the unborn child. If the subject is of childbearing age and if the subject decides to participate in this study, the subject should use one of the approved methods of contraception to avoid becoming pregnant during the study. The doctor will discuss with the subject the different options that are indicated.

3. Risks associated with the evaluation procedures specific to the study
If the subject is assigned to the spinal cord stimulation test group, they will have X-rays taken during the surgery and possibly after activation of the device, to check the electrodes. If the subject is assigned to the control group, they may also need X-rays. For both groups this will be done according to the ususal practice of the pain center and the risk is the same even if the subject did not participate in this study.
Further more, this study collects data via questionnaires and no tests are taken.

# Contacts

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

## Inclusion criteria

A subject must MEET ALL of the following 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, 6 months refractory to conventional therapy 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 inform 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

## Exclusion criteria

A subject must NOT MEET ANY of the following 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 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.)

# Study design

## Design

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|---|---|
| Study phase: | 4 |
| Study type: | Observational non invasive |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |
| Primary purpose: | Treatment |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 25-02-2021 |

| | |
|---|---|
| Enrollment: | 20 |
| Type: | Actual |

### Medical products/devices used

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|---|---|
| Generic name: | IntellisTM neurostimulator |
| Registration: | Yes - CE intended use |

## Ethics review

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|---|---|
| Approved WMO Date: | 03-02-2021 |
| Application type: | First submission |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO Date: | 23-02-2021 |
| Application type: | Amendment |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

| Register | ID |
|---|---|
| ISRCTN | ISRCTN10663814 |
| CCMO | NL74986.091.20 |