A feasibility study regarding physical activity in Spinal Cord Stimulation for patients with Failed Back Surgery Syndrome

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21829

Source
Nationaal Trial Register

Brief title
TBA

Health condition

Patients suffering FBSS with low back pain and/ or leg pain

Sponsors and support

Primary sponsor: Radboudumc, Nijmegen, The Netherlands
Source(s) of monetary or material Support: No funding

Intervention

Outcome measures

Primary outcome

- The feasibility of collecting objective data of the AdaptiveStim™, externally located on the

left buttock and internally placed in the left buttock, measured physical activity in different body positions.
- The feasibility of collecting objective data of the smartwatch measured physical activities and bodily functions before and after SCS implant.
- Overview of the self-supporting questionnaires before and after SCS implant.

Secondary outcome

- Overview of the diagram of Positive Health before and after SCS implant.
- Codes and themes derived from face to face in-depth interviews guided by the diagram of Positive Health by Huber et al.
- Overview of the evaluation forms from patients and clinicians

Study description

Background summary

Patients who suffer from Failed Back Surgery Syndrome (FBSS) experience chronic pain in the low back region and/or lower extremity, often resulting in diminished physical activity. It is known that FBSS affects all domains of life, although these impairments remain difficult to quantify even when they receive Spinal Cord Stimulation (SCS).
Currently, the evaluation of the clinical outcomes of SCS therapy in patients with FBSS is mostly done by standardized pain and quality of life measurements instruments, which hardly account for personal feelings and needs regarding physical activity.
The Intellis AdaptiveStim™ SCS system has an accelerometer to collect objective data of the body positions, while a smartwatch gives objective data of the bodily functions.
To use both tools, we aim to get new insights into the physical activity of FBSS patients before and after the implantation of the SCS.

Study objective

We hypothesize that collecting objective data from 1) the AdaptiveStim™ SCS system and 2) a smartwatch contribute to evaluating the physical activity of FBSS patients. We also hypothesize that qualitative semi-structured interviews based on the six dimensions of the Positive Health model of Huber et al. contribute to the evaluation of patients experiences, objectives and future aims regarding SCS therapy of FBSS patients.

Study design

T= -21 days before SCS implant
T= end trial period
T= 3 month FU

Intervention

T= -21 days before the implant of the SCS. Collecting data:
- Unsterile Intellis AdaptiveStim™ placed on the left buttock + smartwatch
- Self-supporting questionnaires (Visual Analogue Scale (VAS), EuroQol 5D (EQ-5D), Medical Outcome Study-Short Form-36 (MOS- SF 36), Mc Gill Pain Questionnaire, Hospital Anxiety and Depression Scale (HADS), Pain Catastrophizing Scale (PCS), Oswestry) + medication list
- Diagram of Positive Health and perform a face to face in-depth interview

T= end of trial period. Collecting data:
- Smartwatch
- VAS and medication list.
- Diagram of Positive Health

T= 0 implant Intellis AdaptiveStim™ in the left buttock at the same location where the unsterile battery was located.

T= FU 3 month SCS: Collecting data:
- Intellis AdaptiveStim™ + smartwatch
- Self-supporting questionnaires (Visual Analogue Scale (VAS), EuroQol 5D (EQ-5D), Medical Outcome Study-Short Form-36 (MOS- SF 36), McGill Pain
Questionnaire, Hospital Anxiety and Depression Scale (HADS), Pain Catastrophizing Scale (PCS), Oswestry + medication list
- Diagram of Positive Health and perform a face to face in-depth interview
- Evaluation form for patients and clinicians

Contacts

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Eligibility criteria

Inclusion criteria

- Age between 18 and 75 years
- Diagnosed with a Failed Back Surgery Syndrome with low back pain and leg pain. Pain radiating in lumbar segments L4, L5 and S1
- Experienced chronic pain for ≥ six months with a pain score ≥ 5 for the weighted Visual Analogue Scale (VAS)
- No option for further surgical intervention
- Previous pain treatments have been unsuccessful (insufficient pain relief or unacceptable side effects)
- Psychological screened-
- Willing to provide informed consent

Exclusion criteria

- Presence of any other clinically significant or disabling chronic pain condition
- The expected inability of the patients to properly operate the neurostimulation system
- An SCS procedure in the history
- Addiction to drugs, alcohol (≥ 5 E / day) or medication
- Insufficient cooperation (little motivation, understanding)
- History of coagulation disorders, lupus erythematosus, diabetes mellitus, rheumatoid arthritis or Morbus Bechterew
- Current use of medication affecting coagulation which cannot be temporarily stopped
- Unable to speak or understand the Dutch language
- Life expectancy < 1 year
- Pacemaker
- Local infection or other skin problems in the operation area
- Existing or planned pregnancy

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	N/A: single arm study
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2021
Enrollment:	20
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	24-02-2021
Application type:	First submission

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
NTR-new	NL9301
Other	Radboudumc, Nijmegen, The Netherlands : CMO: 2020-6576

Study results