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

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21829

Bron
NTR

Verkorte titel
TBA

Aandoening

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

Ondersteuning

Primaire sponsor: Radboudumc, Nijmegen, The Netherlands
Overige ondersteuning: No funding

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- 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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd

Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-03-2021
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	24-02-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9301
Ander register	Radboudumc, Nijmegen, The Netherlands : CMO: 2020-6576

Resultaten