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The TRIAL-STIM Study

Submission date
03/07/2017

Recruitment status
No longer recruiting

Registration date
15/08/2017

Overall study status
Completed

Last Edited
18/09/2024

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims
Spinal Cord Stimulation (SCS) is the recommended treatment for severe nerve pain. SCS involves implanting a wire through the skin and into the spine; this then attaches to a battery placed under the skin of the stomach. Electric pulses transmitted via this wire to the nerves provide pain relief. This treatment is only recommended for use in the NHS if patients report pain relief from a 'trial' (or test) stimulation where a temporary implanted spine wire is attached to an external battery. The standard practice is for patients to test the system at home for up to 4 weeks. Those experiencing 50% or more pain relief are offered a permanent implanted battery. Although test stimulation is a widely accepted part of clinical practice the scientific evidence for its use is lacking. It is possible that a proportion of patients who fail to experience pain relief during a trial would experience pain relief after a permanent implant. Trials expose patients to an increased risk of infection, pain and increased costs. The aim of this study is to look at the best way to perform the screening trial for patients, either the standard practice or an on-table trial. In the on-table trial patients still have the wires implanted in their back but they try the stimulation in theatre. If they like the sensation, and the painful area is covered with the stimulation, the battery can be implanted at the same time.

Who can participate?
Patients aged 18 and over with persistent pain for more than 6 months who are candidates for SCS

What does the study involve?
Participants are randomly allocated to undergo either the standard practice trial or the on-table trial. Pain, quality of life and costs are assessed by questionnaire at the start of the study and after 3 and 6 months.

What are the possible benefits and risks of participating?
The specific risks for implantation of a Spinal Cord Stimulator are a 0.5% risk of severe headache (known as post-dural puncture headache), a 5% risk of infection and a 10% possibility of the lead moving position or breaking requiring further surgery. Severe complications such as nerve damage are rare. The risks of this surgery are no higher or lower as a result of taking part in the study than anyone else having a spinal cord stimulator implanted.

Where is the study run from?
1. The James Cook University Hospital (UK)
2. Basildon and Thurrock University Hospital (UK)
3. Seacroft Hospital (UK)

When is the study starting and how long is it expected to run for?
July 2015 to December 2019

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
1. Prof. Sam Eldabe
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2. Morag Brookes

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number

33619

Study information

Scientific Title
Does a screening trial for spinal cord stimulation in patients with chronic pain of neuropathic origin have clinical utility and cost-effectiveness?

Acronym
TRIAL-STIM

Study objectives
A no SCS screening trial strategy will be clinically superior to a SCS screening trial and more cost-effective.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North East –Tyne and Wear South Research Ethics Committee, 04/04/2017, ref: 17/NE/0056

Primary study design
Interventional

Study design
Randomised; Both; Design type: Screening, Device, Psychological & Behavioural, Surgery, Qualitative

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Specialty: Anaesthesia, perioperative medicine and pain management, Primary sub-specialty: Anaesthesia, Perioperative Medicine and Pain Management; UKCRC code/ Disease: Neurological/ Nerve, nerve root and plexus disorders

Interventions
Participants are randomly allocated to groups. Randomisation is achieved by means of a password-protected web-based system developed and maintained by Exeter Clinical Trials Unit (ExeCTU). Once the patient has completed the screening interview and baseline data collection interview, the researcher access the randomisation website using a unique username and password. The website requires entry of the study site, participant initials and participant age before returning the participants' unique randomisation number and allocation (Engager Intervention or Control). Allocation is stratified by centre and minimised on patient age (>65 or <65years), gender, and presence of failed back surgery syndrome (FBSS) (or not) use of HF10 or not. Allocation concealment is maintained by only revealing allocation of each participant to the study manager following completion of written informed consent and baseline outcomes.

Usual Care: Screening trial and implantation
Participants randomised to this arm receive a screening trial. A screening trial consists of

passage of either an external or internalised tunnelled SCS lead or leads attached to an external stimulator as per centre's routine practice. Those participants that have a successful screening trial receive an implantable neurostimulation system while unsuccessful patients would not receive such an implant. Taking into consideration the RCTs included in the clinical evidence section of NICE TA159, a successful screening trial is defined as ≥50% pain relief and satisfactory on table paraesthesia coverage (i.e. ≥80%) of the pain area or successful location of leads at anatomical target for paraesthesia free therapies. Patients with an unsuccessful screening trial will not be implanted but all participants continue to be followed-up to six-months.

Intervention: Implantation only strategy
In the implantation only strategy group, all participants with satisfactory on table paraesthesia coverage (i.e. ≥80%) of the pain area and no dislike of sensations, and satisfactory anatomical lead location for paraesthesia free devices would receive a permanent implant.

Patient outcome measures are collected at clinic visits at baseline (pre-randomisation), and at three and six-month follow-up measured from date of trial or permanent implant. The semi-structured interviews are carried out in a cohort of 32 subjects before and one-month following implantation or trial exit.

Intervention Type
Other

Primary outcome(s)
Pain is measured on a Numerical Rating Scale (NRS) at 6 months, with a minimal clinically important difference (MCID) of 2 points between the two randomised treatment arms

Key secondary outcome(s)
1. The proportion of patients achieving at least 50% and 30% pain relief at 6 months, measured on the NRS at baseline, 3 and 6 months
2. Health related quality of life is measured using the EQ-5D-5L at baseline, 3 and 6 months
3. Function is measured using the Oswestry Disability Index (ODI) questionnaire at baseline, 3 and 6 months
4. Patient satisfaction is measured using the Patients' Global Impression of Change (PGIC) questionnaire at 3 and 6 months
5. Complication rates are measured using Adverse Events recording at each visit
6. Patients' views of the screening trial, implantation and overall use of the device, assessed using a semi-structured interview for 30 patients (10 at each centre) at baseline and 1 month post implant by telephone

Completion date
02/12/2019

Eligibility

Key inclusion criteria
1. Adults (≥18 years) who are clinically considered to be candidates for SCS as per NICE TA159
2. Pain of neuropathic nature of an intensity of at least 5 as assessed on a numerical rating scale (NRS)
3. Patient has persistent pain for more than 6 months despite appropriate conventional medical and surgical management including (TENS), acupuncture, oral analgesic agents, cognitive behavioural therapy as well as nerve blockade where appropriate

4. Satisfactory multidisciplinary assessment by a team with expertise in delivering SCS therapy
5. Capable of providing informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
107

Key exclusion criteria
1. Patient refusal to participate in the study
2. Presence of an on-going pain condition considered by the investigator to overshadow the neuropathic pain condition to be treated with SCS
3. Current or previous treatment with an implanted pain relief device
4. Current participation or planned participation in other studies that may confound the results of this study
5. Ongoing anticoagulation therapy, which cannot be safely discontinued
6. Poor cognitive ability
7. Unable to undergo study assessments or complete questionnaires independently
8. Patient is pregnant or planning to become pregnant during the course of the study

Date of first enrolment
06/06/2017

Date of final enrolment
01/01/2019

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
The James Cook University Hospital
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Study participating centre
Basildon and Thurrock University Hospital
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Study participating centre
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Sponsor information

Organisation
James Cook University Hospital

ROR
https://ror.org/02vqh3346

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2020	14/01/2021	Yes	No
Results article	results	01/12/2020	14/01/2021	Yes	No
Results article	36-Month Results	01/01/2023	18/09/2024	Yes	No
Protocol article	protocol	16/11/2018		Yes	No
HRA research summary			28/06/2023	No	No