# The TRIAL-STIM Study

Submission date 03/07/2017	<b>Recruitment status</b> No longer recruiting	<ul><li>[] Prospectively re</li><li>[X] Protocol</li></ul>
Registration date 15/08/2017	<b>Overall study status</b> Completed	<ul><li>[] Statistical analy</li><li>[X] Results</li></ul>
Last Edited 18/09/2024	<b>Condition category</b> Surgery	Individual partic

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### 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 seldabe@nhs.net 2. Morag Brookes

# **Contact information**

**Type(s)** Scientific

**Contact name** Prof Sam Eldabe

# **Contact details**

Cheriton House The James Cook University Hospital Marton Road Middlesbrough United Kingdom TS4 3BW

# Type(s)

Scientific

**Contact name** Miss Morag Brookes

### **Contact details**

TRIAL-STIM Study Manager The James Cook University Hospital Cheriton House Marton Road Middlesbrough United Kingdom TS4 3BW

# Additional identifiers

EudraCT/CTIS number

**IRAS number** 

ClinicalTrials.gov number

Secondary identifying numbers 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?

TRIAL-STIM

### **Study objectives**

A no SCS screening trial strategy will be clinically superior to a SCS screening trial and more costeffective.

**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

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

**Primary study design** Interventional

**Secondary study design** Randomised controlled trial

**Study setting(s)** Hospital

**Study type(s)** Treatment

### Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

# 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 measure

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

### Secondary outcome measures

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

Overall study start date

24/07/2015

# **Completion date**

02/12/2019

# Eligibility

# Key inclusion criteria

Adults (≥18 years) who are clinically considered to be candidates for SCS as per NICE TA159
 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 therapy5. Capable of providing informed consent

# Participant type(s)

Patient

**Age group** Adult

**Lower age limit** 18 Years

**Sex** Both

**Target number of participants** Planned Sample Size: 100; UK Sample Size: 100

# 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** England

United Kingdom

### Study participating centre

**The James Cook University Hospital** Cheriton House Marton Road Middlesbrough United Kingdom TS4 3BW

#### **Study participating centre Basildon and Thurrock University Hospital** Nethermayne Basildon United Kingdom SS16 5NL

**Study participating centre Seacroft Hospital** York Road Leeds United Kingdom LS14 6UH

# Sponsor information

Organisation

James Cook University Hospital

#### Sponsor details

Research and Development Department Marton Road Middlesbrough England United Kingdom TS4 3BW

Sponsor type

Hospital/treatment centre

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**

#### Publication and dissemination plan

The trialists are currently in the process of preparing the protocol publication. Following this they intend to publish the results in a high impact peer reviewed journal. In addition they also intend to present findings at national and International conferences as appropriate.

### Intention to publish date

### 31/05/2021

### 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?
<u>Protocol article</u>	protocol	16/11/2018		Yes	No
<u>Results article</u>	results	01/12/2020	14/01/2021	Yes	No
<u>Results article</u>	results	01/12/2020	14/01/2021	Yes	No
HRA research summary			28/06/2023	No	No
<u>Results article</u>	36-Month Results	01/01/2023	18/09/2024	Yes	No