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Spinal cord stimulation therapy for patients with spinal cord injury suffering from nerve pain which has not responded to usual treatment

Submission date
22/11/2023

Recruitment status
No longer recruiting

Registration date
08/12/2023

Overall study status
Completed

Last Edited
13/02/2024

Condition category
Injury, Occupational Diseases, Poisoning

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Around 40,000 people in the UK are living with long-term disability due to spinal cord injuries, and approximately 40-50% of these people will suffer from neuropathic pain. Spinal cord stimulation is a treatment which has been shown to alleviate chronic neuropathic pain. The primary aim of the study is to ease the pain the participant has. The specific stimulation therapy used in this study is called 'closed loop' stimulation; this means that the stimulation device can measure electrical activity from the spinal cord and use this information to alter the treatment which is given to the patient. The device can also be used to measure any electrical activity in the spinal cord which is below the level of the spinal cord injury; this will include any electrical activity which occurs normally below the injury and any activity which is caused by the spinal cord stimulation therapy.

Who can participate?
People aged 18 years old and over who have a spinal cord injury at the level of T12/L1 or above, and have had the injury for at least 2 years.

What does the study involve?
Participants will have temporary stimulation for a week to two weeks to see if it helps reduce their pain. This involves going to the operating theatre and having two leads inserted into the spine to provide stimulation. These leads are linked to a temporary external stimulator. If the stimulation works and reduces their pain level by 50% or more, they will have the full implant fitted; this involves going to theatre and having the leads attached to a stimulator which will be inserted under the skin on either the tummy or chest wall (the location will be decided between the participant and the implanting doctor for whichever will be the most comfortable site). The participant will be followed up by study staff for 6 months. If the stimulator has been helpful for them, they can still use it after the study and will be looked after by the team in the Pain Clinic.

What are the possible benefits and risks of participating?
The benefit to the participant is the chance of having effective pain reduction from the device. Risks to the patient are the same as for anyone who receives spinal cord stimulation therapy;

these risks are 0.5% risk of severe headache (known as post-dural puncture headache), 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.

Where is the study run from?
The James Cook University Hospital, Middlesbrough (UK)

When is the study starting and how long is it expected to run for?
May 2022 to June 2026

Who is funding the study?
Saluda Medical Europe Ltd (UK)

Who is the main contact?
Dr Anu Kansal, a.kansal@nhs.net

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
320715

Central Portfolio Management System (CPMS)
59247

Study information

Scientific Title

A prospective trial to assess evoked electrical activity above and below spinal cord injury lesions using the EVOKE™ spinal cord stimulator

Acronym
PRACTICAL

Study objectives
There is no formal study hypothesis - this is an investigational study to evaluate the impact of spinal cord stimulation using a closed-loop system therapy for the alleviation of chronic neuropathic pain in patients with an incomplete or complete spinal cord injury. The primary outcome is to measure the change in pain in the target area.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 11/12/2023, Health and Social Care Research Ethics Committee B (HSC REC B) (Office for Research Ethics Committees Northern Ireland (ORECNI), Business Services Organisation, Unit 4, Lissue Industrial Estate West, Rathdown Walk, Moira Road, , , email , Tel , Lisburn, BT28 2RF, United Kingdom; +44 (0)28 95 361403; recb@hscni.net), ref: 23/LO/0909

Primary study design
Interventional

Study design
Non-randomized cohort study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic neuropathic pain in patients with an incomplete or complete spinal cord injury

Interventions
Patients will be referred to the study from the spinal injuries unit at the centre. If they fullfil the entry criteria and would like to participate, they will be given all information to allow for informed consent. When consented and baseline evaluation of pain and function has been measured, they will have a 'trial' of spinal cord stimulation. This involves the insertion of two leads into area around the spinal cord, similar to having an epidural. This is done in theatre, under local anaesthetic. This is linked to an external device, and the lead insertion points covered with a sterile dressing. Patients go home to receive the trial of therapy for 7-10 days. If they have no or a poor response to the stimulation, the leads will be removed and they will exit the study. If they perceive a improvement in their pain, then the surgeon will implant the battery device under the skin in a place which is comfortable for the patient. Nothing is left above skin level. The device is then programmed to provide the patient with pain relief. After 10 days when the wound has healed, the device is switched on. Patients are then followed up by clinical staff at 1, 3 and 6 months, and outcomes such as pain, function and quality of life will be recorded through the use of questionnaires. Reflexes and neurological function will also be measured.

Information from the devices will be captured and analysed for neurological function. At the end of the study period, the device will remain in situ and active, unless either it needs to be removed for a clinical reason, or the participant requests its removal.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
EVOKE™ spinal cord stimulator

Primary outcome(s)
Pain measured using the visual analogue score (VAS) at baseline, end of the trial, at 1, 3 and 6 months, and any unscheduled visits. It will also be collected in a pain diary four times per day during the trial period.

Key secondary outcome(s)
1. Impairment due to spinal injury measured using the American Spinal Injury Association (ASIA) Impairment Scale (AIS) at baseline, 3 and 6 months
2. Neurological pain measured using the Douleur-Neuropathique-4 (DN-4) questionnaire at baseline, end of trial assessment, 3 and 6 months
3. Spasticity measured using the Modified Ashworth Scale and the Penn Spasm Frequency Scale at baseline, end of trial assessment, 3 and 6 months
4. Disability measured using the Spinal Cord Independence Measure (SCIM) at baseline, end of trial assessment, 3 and 6 months
5. Health status measured using the European Quality of Life-5 Dimensions - EQ-5D-5L at baseline, end of trial assessment, 3 and 6 months
6. Change from Baseline in the general state of health measured using the Patient Global Impression of Change instrument (PGIC) at 6 months
7. Change from Baseline in the general state of health measured using the Clinician* Global Impression of Change instrument (CGIC) at 6 months; *Clinician: both pain physician and SCI specialist to complete
8. Depression measured using the Beck Depression Inventory II at 6 months
9. Sleep disturbance measured using the Pain and Sleep Questionnaire three-item Index (PSQ-3) at baseline, end of trial assessment, 3 and 6 months
10. Medication use measured at every visit
11. Assessment of subject's satisfaction with therapy (assessed by a Subject Satisfaction Questionnaire) at 6 months using 7 point Likert scale

Completion date
01/06/2026

Eligibility

Key inclusion criteria
1. A spinal cord injury (complete or incomplete lesion) of at least 2 years
2. Injury at T12/L1 or above
3. A disability grade on the American Spinal Injury Association (ASIA) Impairment Scale (AIS) of A, B, C or D as determined by a qualified examiner

4. Neuropathic pain as determined clinically by the investigator at or below the level of the SCI
5. Average pain intensity for the target pain area of > = 5 out of 10 cm on the Visual Analogue Scale (VAS) at enrollment when the patient is taking medication
6. Stable chronic pain for at least 4 weeks
7. Refractoriness to pain treatment as determined by the Investigator (which can include medication and/or other treatment modalities)
8. On stable pain medications, as determined by the Investigator, for at least 4 weeks prior to the Baseline Visit
9. An appropriate candidate for EVOKE™ Spinal Cord Stimulation implant as determined by the Investigator
10. An appropriate candidate for the surgical procedures required in this study based on the clinical judgment of the implanting physician and if applicable per the local regulations
11. An adult (> = 18 years of age) at the time of enrolment
12. Willing and capable of giving written informed consent prior to any investigational related procedure (if not able to write consent will happen through legal or personal representative)
13. Willing and able to comply with study-related requirements, assessments and visits
These decisions are based on the clinical judgement of the investigator.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Evidence of an active disruptive psychological or psychiatric disorder or other known condition significant enough to impact perception of pain, compliance of intervention and/or ability to evaluate treatment outcome, as determined by the investigator in consultation with a clinical psychologist
2. A current diagnosis of a progressive neurological disease such as multiple sclerosis, inflammatory, infective, vascular, demyelinating polyneuropathy, rapidly progressive arachnoiditis, rapidly progressive diabetic peripheral neuropathy, brain or spinal cord tumor, or severe/critical spinal stenosis
3. An invalid AIS (e.g. ASIA motor exam not obtainable)
4. A current diagnosis or condition such as a coagulation disorder, bleeding diathesis, platelet dysfunction, progressive peripheral vascular disease or uncontrolled diabetes mellitus that presents excess risk for performing the procedure as determined clinically by the investigator.
5. A diagnosis that precludes lead placement (e.g. severe scoliosis, presence of metalwork)
6. Radiographic evidence of spinal instability requiring fusion as determined by the Investigator
7. Previous and/or current experience with drug pump and/or neurostimulator or another active implantable device such as a pacemaker
8. Metastatic malignant disease or active local malignant disease

9. A life expectancy of less than 1 year
10. An active systemic or local infection
11. Pregnant (if female and sexually active, subject must be using a reliable form of birth control, be surgically sterile or be at least 2 years post-menopausal)
12. Within 6 months of enrollment a significant untreated addiction to dependency producing medications or have been a substance abuser (including alcohol and illicit drugs)
13. Benefitting within 30 days prior to enrollment from an interventional procedure and/or surgery to treat the targeted pain area
14. Concomitantly participating in another clinical study, or planned to be enrolled in another clinical study
Decisions will be based on the clinical judgement of the investigator.

Date of first enrolment
01/04/2024

Date of final enrolment
01/08/2025

Locations

Countries of recruitment
United Kingdom

Study participating centre
The James Cook University Hospital
Marton Road
Middlesbrough
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TS4 3BW

Sponsor information

Organisation
South Tees Hospitals NHS Foundation Trust

ROR
https://ror.org/02js17r36

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care 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

Funder Name
Saluda Medical Europe Ltd

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to the small number of participants, as the data could potentially be identifiable.

IPD sharing plan summary
Not expected to be made available