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Data collection from the Evoke™ System in the treatment of patients with chronic pain of the trunk and/or limbs

Submission date
24/06/2020

Recruitment status
No longer recruiting

Registration date
07/07/2020

Overall study status
Completed

Last Edited
08/01/2024

Condition category
Signs and Symptoms

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

Plain English summary of protocol

Background and study aims
Chronic pain is pain that is ongoing and usually lasts longer than six months despite medication or treatment. This pain can be a result of illness or injury, or the cause may be unknown or unclear. Spinal Cord Stimulation (SCS), where a device is implanted beneath the skin using surgery and is then used to deliver an electric current to the nerves of the site of the pain, can be used to relieve chronic pain.

Saluda Medical has developed the Evoke™ SCS System, a new type of SCS system, which can make some nerve recordings from the wires while they are in place close to the nerves. The system measures the electrical response from the nerves and uses these to automatically alter the stimulation strength. By keeping the strength of the stimulation within a narrow range the patient no longer feels abrupt changes in stimulation and can move around without over or under-stimulation.

This study aims to collect data from the Evoke™ Closed-Loop SCS system from Saluda Medical to evaluate this system in a 'real-world' setting.

Who can participate?
Adult patients suffering from chronic pain in the trunk and/or limbs who are routinely scheduled for spinal cord stimulation with Saluda Medical System

What does the study involve?
Participants will receive the Evoke™ Spinal Cord Stimulation System for treatment of chronic pain of the trunk and/or limbs. Participation will not involve additional visits, tests nor the completion of any questionnaires. The data will be downloaded from the battery during routine visits over a period of 2 years when the patients normally visit the hospital for follow-up. Participants will be asked for approval to use the data stored in the battery.

What are the possible benefits and risks of participating?
There are no extra risks in taking part in this data collection. The trial will only use data that will be downloaded from the Evoke™ SCS system.

Where is the study run from?
4 hospitals in the United Kingdom

When is the study starting and how long is it expected to run for?
From June 2019 to June 2023

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

Who is the main contact?
Mr Dave Mugan
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
263446

ClinicalTrials.gov number
NCT05272137

Secondary identifying numbers
IRAS 263446

Study information

Scientific Title
Prospective data collection to evaluate the feedback control of the Saluda Medical's Evoke™ Spinal Cord Stimulation System in the treatment of patients with chronic pain of the trunk and /or limbs

Acronym
Evoke™ Data Collection

Study objectives
To evaluate the electrophysiological and device data and the programmability of the Evoke™ Closed-Loop SCS system from Saluda Medical in a 'real-world' setting under normal clinical use.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 05/08/2019, Yorkshire & The Humber - South Yorkshire Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne NE2 4NQ UK; +44 (0)207 1048091; nrescommittee.yorkandhumber-southyorks@nhs.net), ref: 19/YH/0253

Study design
Multicentre prospective observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Chronic pain in the trunk and/or limbs

Interventions
This prospective data collection is purely observational and does not include any intervention. Data collection on the electrophysiological and device data and the programmability of the Saluda Medical EvokeTM Closed-Loop SCS System for the treatment of patients with chronic trunk and/or limb pain followed for 2 years. The data will be automatically downloaded during standard of care visits between baseline and 2 years. The patients will not have any additional visits, questionnaires, or interventions outside the normal standard care.

Intervention Type

Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Saluda Medical Evoke™ Closed-Loop Spinal Cord Stimulation system

Primary outcome measure
Collection of electrophysiological and device data from the EvokeTM ClosedLoop SCS system automatically downloaded during standard of care visits between baseline and 2 years, collected at 2 years

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
17/06/2019

Completion date
30/06/2023

Eligibility

Key inclusion criteria
1. Aged ≥18 years
2. Suffering from chronic pain in the trunk and/or limbs
3. Routinely scheduled for spinal cord stimulation with Saluda Medical System
4. Consent given for prospective data collection and transfer of de-identified data to Saluda Medical

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
500

Total final enrolment
148

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment
25/06/2020

Date of final enrolment
22/11/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Leeds General Infirmary
B Floor, Brotherton Wing
Great George St
Leeds
United Kingdom
LS1 3EX

Study participating centre
Barts Health NHS Trust
St Bartholomew's Hospital
West Smithfield
London
United Kingdom
EC1A 7BE

Study participating centre
North Bristol Trust
Southmead Hospital
Westbury on Trym
Bristol
United Kingdom
BS10 5NB

Study participating centre
South Tees Hospitals
The James Cook University Hospital
Marton Rd

Middlesbrough
United Kingdom
TS4 3BW

Study participating centre
York and Scarborough Teaching Hospitals NHS Foundation Trust
York Hospital
Wigginton Road
York
United Kingdom
YO31 8HE

Sponsor information

Organisation
Saluda Medical Europe Ltd

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Sponsor type
Industry

Website
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Funder(s)

Funder type
Industry

Funder Name
Saluda Medical Europe Ltd

Results and Publications

Publication and dissemination plan
Data will be published at the completion of the study.

Intention to publish date
31/01/2024

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 fact that the device data is collected for sponsor internal use only. The participating sites will be provided with a copy of their data upon request.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			26/07/2023	No	No