

Patient satisfaction with stimulation sensation and coverage comparing single versus dual channel stimulation in the Synergy® system

Submission date 29/09/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 29/09/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 21/04/2015	Condition category Signs and Symptoms	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0227170368

Study information

Scientific Title

Patient satisfaction with stimulation sensation and coverage comparing single versus dual channel stimulation in the Synergy® system

Study objectives

Does dual channel stimulation improve subjective coverage of the pain area with paraesthesias and therefore patient satisfaction with the stimulator?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Signs and Symptoms: Pain

Interventions

20 patients already implanted with Synergy Spinal Cord Stimulation (SCS) device for pain relief will be recruited. Baseline data will be collected for paraesthesia coverage and patient satisfaction (0-100mm line) as well as Global perceived effect (1-7 scale). The patient will then be randomised by means of sealed envelopes to 2 groups.

Group A patients, will be seen by the PI and will have their Synergy device programmed to deliver single channel stimulation for 2 weeks then dual channel stimulation for 2 weeks.

Group B patients will have the opposite sequence. At the end of each 2-week period the questionnaires administered at baseline will be re-administered by a blinded observer.

Patients will be unaware of their mode of programming throughout the study.

Intervention Type

Device

Primary outcome measure

1. Patient satisfaction score (0-100mm line)
2. Paraesthesia coverage (0-100mm line)
3. Global perceived effect (1-7)

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/10/2005

Completion date

31/10/2007

Eligibility

Key inclusion criteria

1. Patient implanted with Synergy stimulator
2. Patient willing to take part in the study

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

Sample size = 20

Key exclusion criteria

1. Patient implanted with single channel stimulator
2. Patient unwilling to take part in the study

Date of first enrolment

01/10/2005

Date of final enrolment

31/10/2007

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
South Tees Hospitals NHS Trust
Cleveland
United Kingdom
TS4 3BW

Sponsor information

Organisation

Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Sponsor details

The Department of Health
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

<http://www.dh.gov.uk/Home/fs/en>

Funder(s)

Funder type

Government

Funder Name

South Tees Hospitals NHS Trust (UK)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration