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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	[ ] Prospectively registered [ ] Protocol
Registration date 29/09/2006	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 21/04/2015	**Condition category** Signs and Symptoms	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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
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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