

A prospective, randomised, controlled, multicentre study to evaluate the effectiveness and cost-effectiveness of spinal cord stimulation using the Synergy™ System in reducing pain in patients with failed back surgery syndrome compared to conventional medical management (PROCESS study)

Submission date 12/06/2003	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 04/07/2003	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 23/07/2009	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

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

NA

Study information

Scientific Title

Acronym

PROCESS

Study objectives

Patients will be randomised to receive either spinal cord stimulation (SCS) or conventional medical management (CMM) for a period of 24 months (1:1 randomisation). Patients receiving SCS will first undergo trial stimulation. In case of less than 80% paraesthesia coverage and/or less than 50% pain relief in the legs following trial stimulation the patients will not undergo the implantation of the Synergy™ stimulator, but will still be followed-up according to the intention to treat principle. At the 6 months visit, a review of the effectiveness of treatment will take place based on leg pain relief. Patients will be classified as successful (i.e. \geq 50% pain relief in the legs) or non-successful (i.e. less than 50% pain relief in the legs). Moreover, the treatment of the patient will be reviewed and patients not successful may switch to the other treatment for the remainder of the study duration (18 months) if deemed necessary by the physician and the patient.

The assumption is that the proportion of patients successfully treated will be 42.5% in the SCS arm and 14.5% in the CMM arm. Patients will be randomised to receive either spinal cord stimulation (SCS) or conventional medical management (CMM) for a period of 24 months (1:1 randomisation). Patients receiving SCS will first undergo trial stimulation. In case of less than 80% paraesthesia coverage and/or less than 50% pain relief in the legs following trial stimulation the patients will not undergo the implantation of the Synergy(tm) stimulator, but will still be followed-up according to the intention to treat principle. At the 6 months visit, a review of the effectiveness of treatment will take place based on leg pain relief. Patients will be classified as successful (i.e. $>50\%$ pain relief in the legs) or non-successful (i.e. less than 50% pain relief in the legs). Moreover, the treatment of the patient will be reviewed and patients not successful may switch to the other treatment for remainder of the study duration (18 months) if deemed necessary by the physician and the patient.

The assumption is that the proportion of patients successfully treated will be 42.5% in the SCS arm and 14.5% in the CMM arm, with a power of 80% and an $\alpha < 0.05$.

The primary aim of the study is to evaluate the clinical effectiveness of spinal cord stimulation using the Synergy(tm) System on leg pain in patients with failed back surgery syndrome of a predominantly neuropathic nature compared to CMM.

The secondary aim of the study is to evaluate the cost effectiveness of spinal cord stimulation using the Synergy(tm) System on pain in patients with failed back surgery syndrome of a predominantly neuropathic nature compared to CMM.

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)

Not Specified

Participant information sheet**Health condition(s) or problem(s) studied**

Failed Back Surgery Syndrome (FBSS), chronic neurophatic pain

Interventions

Treatment A:

Spinal cord stimulation using the Synergy™ Neuromodulation System (Medtronic) including trial stimulation. Patients may receive conventional treatment such as pain medication, physical therapy and/or other therapies on the basis of need and at the discretion of the investigator, but not spinal surgery or intrathecal drug delivery systems

Treatment B:

Conventional medical management, to include physical and psychological therapy/rehabilitation and drug treatment, but not spinal surgery or intrathecal drug delivery systems. The particular package of conventional therapy (drug and non-drug), will be determined by the investigator on the basis of the needs of each patient.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Percentage of patients reporting >50% pain relief in the legs

Secondary outcome measures

Pain relief, health-related quality of life (SF-36 and EQ-5D), functional capacity (Oswestry), patient satisfaction, time away from work, adverse events

Overall study start date

09/04/2003

Completion date

30/06/2005

Eligibility

Key inclusion criteria

1. Male/female between 18 and 65 years
Protocol Amended 07/10/03 - Patients aged 65 and older are also included
2. Bilateral or unilateral chronic neuropathic pain predominantly in the leg(s)(>50%)
3. Pain radiating in dermatome segments L4 and/or L5 and/or S1 for at least 6 months following at least one anatomically successful surgery for a herniated disc
4. Pain intensity assessed by visual analogue scales (VAS) >5 (50%)
5. Willing to provide informed consent

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

100

Key exclusion criteria

1. Predominantly back pain (>50%)
2. Presence of any other clinically significant or disabling chronic pain condition
3. Expected inability of patients to receive or properly operate the spinal cord stimulation system
4. History of coagulation disorders, lupus erythematosus, diabetic neuropathy, rheumatoid arthritis or morbus Bechterew
5. Active malignancy
6. Current use of medicines affecting coagulation which cannot be temporarily stopped
7. Evidence of an active disruptive psychiatric disorder or other known condition significant enough to impact the perception of pain, compliance to intervention and/or ability to evaluate treatment outcome as determined by the investigator
8. Life expectancy of less than 1 year
9. Existing or planned pregnancy

Date of first enrolment

09/04/2003

Date of final enrolment

30/06/2005

Locations

Countries of recruitment

Canada

Study participating centre**Department of Neurosurgery**

Regina, Saskatchewan

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Sponsor information

Organisation

Medtronic Europe sarl

Sponsor details

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Sponsor type

Not defined

ROR

<https://ror.org/00grd1h17>

Funder(s)

Funder type

Industry

Funder Name

Medtronic Europe Sàrl (Switzerland)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2007		Yes	No
Results article	results	01/05/2009		Yes	No