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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

Registration date
04/07/2003

Overall study status
Completed

Last Edited
23/07/2009

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Krishna Kumar

Contact details
Department of Neurosurgery
Regina General Hospital
1440 - 14th Avenue
Regina, Saskatchewan
Canada
S4P 0W5
+1 306 781 61 16
krishna.kumar@rqhealth.ca

Additional identifiers

Protocol serial number
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. ? 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

Study type(s)
Not Specified

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

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

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 dermatomo 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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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
Canada
S4P 0W5

Sponsor information

Organisation
Medtronic Europe sarl

ROR
https://ror.org/00grd1h17

Funder(s)

Funder type
Industry

Funder Name
Medtronic Europe Sàrl (Switzerland)

Results and Publications

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