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Percutaneous pulsed radiofrequency treatment for lumbosacral radicular pain at the dorsal root ganglion

Submission date
14/07/2013

Recruitment status
No longer recruiting

Registration date
23/07/2013

Overall study status
Completed

Last Edited
02/09/2020

Condition category
Musculoskeletal Diseases

[ ] 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 lumbosacral radicular pain (a long-lasting radiating pain in the spine) is an important medical and socioeconomic problem. The major cause of the pain is the stimulation of parts of the spine called the nerve root and dorsal root ganglion (DRG) by disc herniation (also known as a slipped disc, where one of the discs in the spine ruptures and the gel inside leaks out). Continuous and pulsed radiofrequency procedures have been used at the DRG to reduce the radiating pain; several studies show a beneficial result of pulsed radiofrequency treatment at the DRG with no complications.
In this study we will investigate the value of percutaneous pulsed radiofrequency treatment applied to the lumbar and
sacral DRG to try to determine if a significant and long-lasting pain reduction can be obtained as compared to a sham-operated group. In addition, a cost analysis will be performed for each individual treatment as well as for the complete healthcare system. The results will be used for further studies concerning treatment in spine-related pain disorders.

Who can participate?
Patients aged 18 or over with a case history and physical investigation suggestive of lumbosacral radicular pain for more than 3 months .

What does the study involve?
Group 1 (treatment group): percutaneous pulsed radiofrequency treatment at the lumbar and sacral dorsal root ganglion.
Group 2 (sham-operated group): the same procedure as in group 1 without pulsed radiofrequency treatment. Both groups will receive graded activity physiotherapy.

What are the possible benefits and risks of participating?
Until now no complications from percutaneous pulsed radiofrequency treatment have been reported.

Where is the study run from?
Lievensberg Hospital, Bergen op Zoom, The Netherlands and Franciscus Hospital, Roosendaal, The Netherlands.

When is the study starting and how long is it expected to run for?
The study started in July 2013 and will run until July 2015.

Who is funding the study?
Centre for Pain Medicine, Erasmus University MC, Rotterdam, The Netherlands.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NL43783.078.13

Study information

Scientific Title
A randomised sham-controlled double-blind multicenter clinical trial to evaluate the percutaneous Pulsed RadioFrequency treatment at the Dorsal Root Ganglion

Acronym
PRF DRG

Study objectives
Investigate the value of percutaneous pulsed radiofrequency, applied to the lumbar and sacral dorsal root ganglion; more specifically try to determine if a significant and long lasting pain reduction can be obtained as compared to a sham-operated group. In addition to the above a cost analysis will be performed for each individual treatment as well as for the complete healthcare system. The results will be used for further studies concerning intervention in spine related pain disorders.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval has been granted by the Medical Ethics Committee (Medisch Ethische Toetsings Commissie) (METC) Erasmus MC, Rotterdam, The Netherlands on June 6, 2013, reference number MEC-2013-178.

Study design
Randomised sham-controlled double-blind multicenter clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Lumbosacral radicular pain

Interventions
Patients with lumbosacral radicular pain first receive a diagnostic block at the DRG:
1. Diagnostic injection at the DRG:
The diagnostic injection is performed fluoroscopically and by means of a Sluijter-Mehta Kit (SMK) needle (Cotop® via Neurotherm®, Wilmington, Massachusetts, United States) with an overall length of 10 cm. Local anesthesia with 1 mL lidocaine 2% per level is given for skin infiltration. The DRG is infiltrated with a total of 1 mL lidocaine 2% per level. The results of the diagnostic injections are rated according to Ostelo et al. (Ostelo, 2008), in which a positive result is obtained with a reduction in NRS of 2 or more on 10. Patients with a reduction in NRS of less than 2 on 10 drop out of the study.

When patients are candidates for the RCT they are randomized in two study groups:
PRF at the DRG versus sham:

1. Group 1 (treatment group): skin infiltration with 1 mL lidocaine 2% per level, infiltration of the DRG with 1 mL lidocaine 2% per level, percutaneous PRF (45 V, 2 Hz, 4 minutes, maximum of 42o C per level) with the NT2000 laesion generator (Neurotherm®, Wilmington, Massachusetts, United States) at the DRG
2. Group 2: (sham-operated group) same procedure as in treatment group except for PRF. This is followed with graded activity and follow up for both groups.

A crossover is provided for the sham-operated group after three months if no significant pain relief is obtained. The results of the crossover group will be analyzed separately, as well as compared with those who received the actual treatment in the first case.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Pain reduction (NRS) measured on the day of consultation, 1, 3, 6 and 12 months after treatment

Secondary outcome measures
1. Pain: Chronic Pain Acceptance Questionnaire (CPAQ), Four-Dimensional Symptom Questionnaire (4DSQ), Multidimensional Pain Inventory (MPI-DLV); Global Perceived Effect (GPE). Measured on the day of consultation, 1, 3, 6 and 12 months after treatment
2. Disability: Oswestry Disability Index (ODI); measured on the day of consultation, 3 and 12 months after treatment
3. Generic health status: Rand-36; measured on the day of consultation, 3 and 12 months after treatment
4. Kinesiophobia: Tampa Scale for Kinesiophobia (TSK); measured on the day of consultation, 3 and 12 months after treatment
5. Coping: Pain Coping Inventory (PCI), Pain Cognition List (PCL-2003); measured on the day of consultation, 3 and 12 months after treatment
6. Costs of intervention.

Overall study start date
15/07/2013

Completion date
15/07/2015

Eligibility

Key inclusion criteria
1. Age 18 years or older
2. Anamnesis and physical investigation suggestive of lumbosacral radicular pain for more than 3 months
3. Decrease in Numeric Rating Scale (NRS) of 2 or more / 10 on diagnostic block at the DRG

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Presence of red flags: possible fracture (major trauma, minor trauma in elderly or osteoporotic), possible tumor or infection (age >50 or <20, history of cancer, constitutional symptoms (fever, chills, weight loss), recent bacterial infection, IV drug abuse, immunosuppression, pain worsening at night or when supine), possible significant neurological deficit (severe or progressive sensory alteration or weakness, bladder or bowel dysfunction, evidence of neurological deficit (in legs or perineum in the case of low back pain)
2. Aspecific low back pain
3. Corpus vertebrae problem
4. Progressive neurological deficits
5. Major psychiatric disorder (according to psychiatrists opinion)
6. Anticoagulation cannot be stopped
7. Pain in other parts of the body that is more severe (including facet joint -, SI joint - and discogenic pain)
8. Allergies to any medication used in the study
9. Pregnancy
10. Communication (language) difficulties (according to physicians opinion)

Date of first enrolment
15/07/2013

Date of final enrolment
15/07/2015

Locations

Countries of recruitment
Netherlands

Study participating centre
Multidisciplinary pain centre
Bergen op Zoom
Netherlands
4624 VT

Sponsor information

Organisation
Erasmus University Medical Centre (MC) (Netherlands)

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Sponsor type
University/education

Website
http://www.erasmusmc.nl/pijn

ROR
https://ror.org/018906e22

Funder(s)

Funder type
University/education

Funder Name
Centre for Pain Medicine, Erasmus University MC, Rotterdam (Netherlands)

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