

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

Submission date 14/07/2013	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 23/07/2013	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 02/09/2020	Condition category Musculoskeletal Diseases	☐ 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?

C.W.J. van Tilburg, MD, FIPP

vtilburg@ziggo.nl

Contact information

Type(s)

Scientific

Contact name

Dr Cornelis Wilhelmus Jacobus van Tilburg

Contact details

Multidisciplinary pain centre

Lievensberg Hospital

Boerhaaveplein 1

Bergen op Zoom

Netherlands

4624 VT

Additional identifiers

Protocol serial number

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.

Primary study design

Interventional

Study design

Randomised sham-controlled double-blind multicenter clinical trial

Study type(s)

Treatment

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 420 C per level) with the NT2000 lesion 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(s)

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

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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)

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**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration