A randomised, sham-controlled, double-blind, multicenter clinical trial to evaluate the percutaneous pulsed radiofrequency treatment at the dorsal root ganglion

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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...

Ethical review	Approved WMO
Status	Pending
Health condition type	Spinal cord and nerve root disorders
Study type	Interventional

Summary

ID

NL-OMON38908

Source
ToetsingOnline

Brief title
PRF at the DRG

Condition

- Spinal cord and nerve root disorders

Synonym
radiating, Radicular

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Lumbosacral, Pain, Radicular, RCT

Outcome measures

Primary outcome

Numerical Rating Scale (NRS).

Secondary outcome

Pain: Chronic Pain Acceptance Questionnaire (CPAQ), Four-Dimensional Symptom

Questionnaire (4DSQ), Multidimensional Pain Inventory (MPI-DLV); Global

Perceived Effect (GPE).

Disability: Oswestry Disability Index (ODI);

Generic health status: Rand-36;

Kinesiophobia: Tampa Scale for Kinesiophobia (TSK);

Coping: Pain Coping Inventory (PCI), Pain Cognition List (PCL-2003).

Costs of intervention.

Study description

Background summary

chronic lumbosacral radicular pain is an important medical and socioeconomic problem, the major cause of it being stimulation of the nerve root and dorsal root ganglion (DRG) by disc herniation. Continuous (CRF) and pulsed (PRF) radiofrequency procedures have been used at the DRG to diminish the radiating pain; differences between them (electrical and histological - as well as chemical results) are explained. Several studies show a beneficial result of PRF at the DRG with no complications; no randomised controlled trial (RCT) has been conducted.

Study objective

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.

Study design

randomised, sham-controlled, double-blind, multicenter clinical trial.

Intervention

group 1 (treatment group): percutaneous pulsed radiofrequency treatment (45 V, 2 Hz, 20 ms, 4 minutes, maximum 42º C) at the lumbar and sacral dorsal root ganglion; group 2 sham-operated group (same procedure as in group 1 except pulsed radiofrequency). Both groups will receive graded activity physiotherapy.

Study burden and risks

Minimally invasive treatments provide alternatives for lumbosacral radicular pain with the appeal of cost-effectiveness and, possibly, less long-term side effects. Up until now no complications from fluoroscopically guided percutaneous pulsed radiofrequency of the lumbar and sacral dorsal root ganglion have been reported.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

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 NRS of 2 or more / 10 on diagnostic block at the DRG

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 defecits
5) Major psychiatric disorder (according to psychiatrists opinion)
6) Anticoagulation cannot be stopped
7) Active infection
8) Pain in other parts of the body that is more severe (including facet joint -, SI joint - and discogenic pain)
9) Allergies to any medication used in the study
10) Pregnancy
11) Communication (language) difficulties (according to physicians opinion)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2013
Enrollment:	60
Type:	Anticipated

Medical products/devices used

Generic name:	SMK needle
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	06-06-2013
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL43783.078.13