Pulsed radiofrequency treatment of the lumbar dorsal root ganglion for patients with chronic lumbosacral radicular pain.

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To evaluate the effect of PRF treatment adjacent to the lumbar dorsal root ganglion (DRG) of L5 or S1 in patients with a chronic LRS.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Peripheral neuropathies
Study type	Interventional

Summary

ID

NL-OMON38414

Source
ToetsingOnline

Brief title
PRF of lumbosacral radicular pain

Condition

- Peripheral neuropathies

Synonym
Chronisch lumbosacraal syndroom

Research involving
Human

Sponsors and support

Primary sponsor: Dienst anesthesie - pijntherapie
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Dorsal root ganglion, Pain, Pulsed radiofrequency, Radicular

Outcome measures

Primary outcome

The primary research question is to evaluate the extent of additional pain reduction induced by PRF, compared with the control group. Following evaluation tools are used: Visual Analogue Scale 8, Global Perceived Effect on Likert Scale, consumption of pain medication, neuropathic pain scales: LANSS and DN-4.

Secondary outcome

Secondary parameters are quality of life measured by RAND 36, disability measured with the Oswestry disability Index.

A sub-analysis will be conducted to evaluate a potential correlation between diagnostic block and outcome of PRF treatment. Another sub-analysis will be conducted to evaluate a potential correlation between the neurological tests described in this study and the outcome of PRF treatment.

Study description

Background summary

Lumbosacral radicular syndrome (LRS) is probably the most frequent neuropathic pain syndrome, however the available evidence for currently used treatments is scares. The beneficial effect of pulsed radiofrequency (PRF) treatment has been described for the management of LRS in case reports, retrospective and prospective studies.

Study objective

To evaluate the effect of PRF treatment adjacent to the lumbar dorsal root ganglion (DRG) of L5 or S1 in patients with a chronic LRS.

Study design

Prospective multicenter clinical trial. The study will be performed in third line referral centers. Conventional medical management will be optimized in all patients during at least 1 month. The patients who still have a pain score for their leg pain >5 (VAS) are candidates for the PRF study. After informed consent, the patients receive a diagnostic block and treatment with PRF.

Intervention

Initially conventional medical management (CMM) will be optimized in all patients during at least one month. All applicable patients, with NRS score above 5, will receive PRF treatment adjacent to the DRG of L5 or S1 additionally to CMM, after a diagnostic block. When no satisfaction in painreduction is reached (after 6 weeks) a second PRF treatment is possible. The second group (Control group) will continue CMM during the study period.

Study burden and risks

Patients will undergo a neurologic examination before and 4 weeks after the intervention; this will be repeated at 3 and 6 months if abnormalities are observed. At each of these time points the patients will receive questionnaires to fill out. In total 4 times. The PRF group will first receive a diagnostic block.

Possible Risks:
A puncture of a blood vessel is possible, diagnosed by injection of contrast, for which repositioning of the needle is needed.
Should accidental intravascular injection of local anesthetic occur, the dose used is low and reports show that intravascular injection of lidocaine 20mg does not pose clinical problems.
The dura can be punctured; as a consequence contrast will flow in the cerebrospinal fluid. The procedure will be stopped and repeated after a few days.
In theory a lesion of the nerve root is possible, but the needles are designed to avoid this, this complication has not been seen since more than 10 years.
Up till now, a transient pain is occasionally described after the PRF treatment.
No hypoesthesia or motor complications were reported.
So the risks are negligible and the procedures are well tolerated.

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

* Symptoms more than 3 months;
* Pain radiating into the leg, up to the hallux (big toe) (L5) or little toe (S1),
* The pain in the leg dominates over a possible lumbalgia, the average pain in the leg measured 3 times a day, at predefined time points, over 4 consecutive days prior to inclusion should be more than 5 (VAS 10-point scale) 9,
* Pattern of radiation suggestive for L5 or S1 pathology 49,50,
* One or more positive neurological tests of nerve root tension or neurological deficit 51 (straight leg raising test (SLRT), contralateral SLRT, motor block during SLRT and passive cervical flexion, motor reaction during passive cervical flexion while bending forward in standing position),
* Capable of understanding the information relative to the treatment and procedure and willing to provide informed consent,

* Capable of understanding and filling-out the questionnaires necessary for evaluation of the treatments,
* Patients having undergone low back surgery like discectomy with or without laminectomy are allowed to participate in the study.

Exclusion criteria

* Patients younger than 18 years,
* Malignant disorder or currently under treatment for a malignant disorder,
* Previous lumbar fractures,
* Proven myelum lesion or abnormalities in the central neurological structures,
* Systemic or connective tissue diseases,
* Diabetes mellitus type I,
* Multiple sclerosis,
* Coagulation disorders,
* Pregnancy,
* Pain Catastrophizing Scale > 45. When the patient has a higher score he/she will first be referred to a psychologist for consultation 52,
* Leg pain due to localized hip or knee pathology,
* Patients with a pacemaker or neurostimulator,
* Patients previously treated with RF or PRF of the lumbar DRG.

Study design

Design

Study phase:	4
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-07-2010
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	14-12-2009
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	01-12-2010
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	23-01-2012
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL28367.068.09