The effectiveness of a PRF-DRG treatment on radicular neuropathic pain

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Peripheral neuropathies
Study type	Observational non invasive

Summary

ID

NL-OMON40047

Source
ToetsingOnline

Brief title
Effectiveness PRF-DRG

Condition

- Peripheral neuropathies

Synonym
neuralgia, Radicular neuropathic pain

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: - Dorsal root ganglion, - Electric quantitative sensory testing, - Pulsed radiofrequency, - Radicular neuropathic pain

Outcome measures

Primary outcome

Electrical sensation thresholds before and after PRF treatment

Secondary outcome

VAS score, symptoms of pain (pain detect), medication use, HADS and RAND-36

questionnaire

Study description

Background summary

Chronic radicular neuropathic pain originating from lumbar or sacral nerve root is a common neuropathic pain and in some cases difficult to treat. Currently pulsed radiofrequency (PRF) is applied on the dorsal ganglion (DRG) to patients with refractory radicular neuropathic pain. The effectiveness of a PRF treatment is currently determined by a VAS score. A VAS score is subjective. A more objective measurement of pain is desired, this can be by means of electric quantitative sensory testing (eQST). eQST would serve as a measure for different nociceptive sensory and neurophysiological processes.

Study objective

The aim of the research is to study the effectiveness of PRF treatment on radicular neuropathic pain. The effectiveness will be determined by eQST, VAS and RAND-36 values. To evaluate the effectiveness of the PRF treatment, there will be included a control group.
There will also be investigated the correlation between VAS and eQST values and whether the pre-measured eQST could predict the effect of the PRF.

Study design

Prospective intervention study in which patients with radicular neuropathic pain will be followed over time from the PRF treatment till 8 weeks after the PRF treatment. Measurments take place on 4 moments: before (baseline) the PRF

treatment, 30 minutes after (follow-up 1) the PRF treatment , 1 week (follow-up 2) and 8 weeks (follow-up 3) after PRF treatment.

Study burden and risks

A low impact, short-term method is chosen for the eQST. The eQST measurements occur during treatment visits and during visits on the pain policlinic, so the patients need to come only 4 time extra for the eQST measurement. In total the patient gets 7 times a eQST measurement. The risks are negligible to mention. In addition, the used eQST method is non-invasive and takes little time to complete the measurement. The psychological and physical stress level of fill in the questionnaires is judged to be low. These questionnaires are regularly in daily clinical practice and can be performed quickly and efficiently. The questionnaires are: VAS score, symptoms of pain (pain detect), medication use and RAND-36 questionnaires and one time the HADS.

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

-Subjects should have lumbar of sacral radicular neuropathic pain in dermatome L4, L5 or S1 where the pain is limited for 1 dermatome for at least 3 months. The subjects should have a pain reduction of minimum 50% with a VAS score from 0 to 10 after a diagnostic block.
- Subject is between 18 and 75 year
- Subject has a pain score of 4 or above (visual analog scale, VAS: 0-10 from no pain to worst pain).
- Subject has no new pain medication 2 weeks before the treatment.
- Informed consent.

Exclusion criteria

- Subject has sensory deficits at the QST site resulting from such medical conditions such as diabetes, alcoholic neuropathy, AIDS neuropathy, severe thyroid, liver or kidney diseases.
- Former PRF and RF treatment of the same nerve root.
- Subject has scar tissue, infection, or acute injury at the QST site.
- Language barriers and other problems impairing the reliable completion of questionnaires.
- Subject is pregnant.
- Subject has a pacemaker.
- Subject has a major psychiatric disease or dementia.
- History of back surgery.
- Other chronic pain (such as fibromyalgia).
- Anticoagulation in form of vitamin K antagonists which should not be stopped.
- Skin diseases (such as herpes zoster, burns etc.)
- Allergy for contrast or lidocaine

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-03-2013
Enrollment:	46
Type:	Actual

Medical products/devices used

Generic name:	Pulsed radiofrequency
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	29-01-2013
Application type:	First submission
Review commission:	METC Twente (Enschede)

Approved WMO

Date:	28-03-2013
Application type:	Amendment
Review commission:	METC Twente (Enschede)

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
Other	3763
CCMO	NL42777.044.12