The effectiveness of a pulsed radiofrequency treatment on radicular neuropathic pain.

Gepubliceerd: 20-12-2012 Laatst bijgewerkt: 13-12-2022

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON20488

Bron
NTR

Verkorte titel
Effectiness PRF-DRG

Aandoening

-Pulsed radiofrequency treatment
-Radicular neuropathic pain

- Gepulseerde radiofrequentie behandeling
- Radiculaire neuropathische pijn

Ondersteuning

Primaire sponsor: Medisch Spectrum Twente (MST)
Overige ondersteuning: N.A.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Electrical quantitative sensory testing values before and after treatment.

Toelichting onderzoek

Achtergrond van het onderzoek

Chronic radicular neuropathic pain originating from lumbar or sacral nerve root is a common neuropathic pain and in some cases diffult to treat. Currently PRF is applied on the 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 subjective measurement of pain is desired, this can be by means of electric quantitative sensory testing (eQST). The aim of the research is to study the effectiveness of PRF treatment on radicular neuropathic pain and to study if the eQST is more accurate and reliable than the VAS score.

Doel van het onderzoek

8 weeks after the PRF treatment we expect that the electric quantitative sensory testing (eQST) values are higher compared to the eQST values before the PRF treatment. This means that patients can tolerate a higher stimulation threshold. The difference in eQST values between the eQST before treatment en 8 week after treatment, will be higher compared to the difference in eQST values for the shamtreatment where only lidocaine is injected.

Onderzoeksopzet

The eQST and VAS score will be performed after the diagnostic block. When the diagnostic block is positive (> 50% pain reduction), the patient will be randomised for or the lidocaine treatment or the PRF treatment. Before the treatment the eQST will be performed. The patient handed in the pain detect questionnaire, VAS score, RAND-36 questionnaire and HADS questionnaire. Furthermore the medication use will be noted.
After the treatment the VAS score and eQST will be performed.

After 1 week, 8 weeks, half year and a year after the treatment the patient handed in pain detect questionnaire, VAS score, RAND-36 questionnaire, medication use and the eQST will be performed. 1 week after the treatment the patient does not handed in the RAND-36 questionnaire.

Onderzoeksproduct en/of interventie

The intervention which will be studied is Pulsed radiofrequency treatment (PRF) on the dorsal

root ganglion (DRG) by patients with radicular neuropathic patients. PRF uses radiofrequency current in short (20 ms), high-voltage bursts; the “silent” phase (480 ms) of PRF allows time for heat elimination, generally keeping the target tissue below 42° C for 120 seconds. During the PRF treatment lidocaine will be injected.

The control intervention which will be studied is lidocaine treatment. During this treament lidocaine will be injected. It will be performed as same as the PRF treament whitout the radiofrequency current.

The effectiveness will be determined by electric quantitative sensory testing (eQST). sQST consisted of determining thresholds to transcutaneous constant current electric stimulation. eQST values will be determined before PRF/sham treatment, after treatment, 1 week, 8 weeks, half year and a year after treatment.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen

(Inclusiecriteria)

Subject should have lumbar or sacral radicular neuropathic pain in dermatome L4, L5 or S1 where the pain is limited for 1 dermatome for at least 3 month. The subject should have a pain reduction of minimum 50% with a VAS score from 0 to 10 after a diagnostic block.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. 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;

2. Former PRF or RF treatment of the same nerve root;

3. Subject has scar tissue, infection or acute injury at the QST site;

4. Language barriers and other problems impairing the reliable completion of questionnaires;

5. Subject is pregnant;

6. Subject has a pacemaker;

7. Subject has a major psychiatric disease or dementia;

8. History of back surgery;

9. Other chronic pain (such as fibromyalgia);

10. Anticoagulation in form of vitamin K antagonists which should not be stopped;

11. Skin diseases (such as herpes zoster, burns etc.);

12. Allergion for contrast or lidocaine.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel

Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-02-2013
Aantal proefpersonen:	46
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	20-12-2012
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3604
NTR-old	NTR3763
Ander register	METC : P12-29
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A