Bipolar Radiofrequency(RF) Lesion of the thoracic medial branch of the posterior ramus for treament of posterior mechanical spinal pain

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Bipolar radiofrequency lesioning of the thoracic medial branch of the dorsal ramus is more effective than a monopolar radiofrequency lesion

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21338

Bron
NTR

Verkorte titel
BiRThoFP

Aandoening

thoracic posterior mechanical (facet) pain
bipolar RF lesion , thoracic facet pain

Ondersteuning

Primaire sponsor: None
Overige ondersteuning: Neurotherm for support in writing the manuscript

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

VAS score
PDI (Pain Disability Index)

Toelichting onderzoek

Achtergrond van het onderzoek

In the general population the prevalence of thoracic pain is estimated to be 13%1. In a population with localized thoracic pain the prevalence of thoracic facet join pain is found to be 42%2

When thoracic facet joint pain proves to be refractory to conventional treatment (medication, physical exercise, TENS) interventional management may be considered. In a recently published randomized controlled trial the effect of infiltration of the medial branch of the thoracic dorsal ramus with local anesthetic with or without corticosteroid was investigated. 3 At 2 years follow-up 80% and 84% of the patients in respectively the group with LA alone and the group treated with LA + corticosteroids. These finding clearly indicate the role of the thoracic facet joints in thoracic pain. Closer analysis of the information, however, shows that patients received a mean of 5.9 injections over the two year study period and the mean duration of pain relief was 18.9 weeks.

Radiofrequency (RF) treatment of the medial branch of the dorsal ramus is well documented for the management of lumbar facet joint pain.4 There is less evidence on the use of RF of the medical branch of the thoracic ramus dorsalis . Positive results up to 2 months after the intervention are documented.5 It has been suggested that increasing the size of the lesion would result in better treatment outcome. 6 Therefore, we assume that using bipolar RF treatment will increase the lesion size and thus improve treatment outcome.

The advantage of bipolar RF over other techniques used to increase the lesion size, such as cooled RF is a better delineation of the lesion, that occurs between the two electrodes.

Doel van het onderzoek

Bipolar radiofrequency lesioning of the thoracic medial branch of the dorsal ramus is more

effective than a monopolar radiofrequency lesion

Onderzoeksopzet

Outcome will be measured 2 months after the procedure. A 6 month follow-up is also scheduled. The first analysis will however be performed at 2 months.

Onderzoeksproduct en/of interventie

The diagnostic process includes identification of the thoracic levels involved in the pain problem. Because the facet joints are innervated from the adjacent cranial and the same level, and in facet pain mostly at least 2 segmental levels are involved, each intervention is performed at least at 3 levels.

The insertion place of the electrode is identified with an AP projection of the C-arm with the patient in a prone position and a metal ruler to find the proper level. A perfect AP fluoroscopic view shows the end plates of the vertebrae to be neatly projected over each other. The transverse processes are identified and the site of insertion of the needles is marked on the skin. An RF needle is inserted parallel to the C-arm projection until contact is made with the bone at the junction between the processus articularis superius and the processus transversus. The needle is then positioned slightly more cranially just abolishing bone contact. With the first needle in place a second needle is inserted using the direction of the first one. The target position is 1 cm parallel of the first needle, also making contact more laterally on the transverse process. At every level to be treated two needles are placed in the similar manner. In a lateral view with the C arm, the tip of the needles should be posterior to the line that connects the posterior aspects of the foramen intervertebrale.

Subsequently, neurostimulation initially takes place with 50 Hz first, then with 2 Hz. The 2 Hz stimulation causes contraction of the paravertebral muscles at intensities below 0.5 to 0.7 V. After local anesthetic is injected, a 180 second bipolar (dual) RF treatment at 80°C is made.

To summarize, the treatment consists of the application of high frequency current at the medial branch of the posterior ramus of at least 3 adjacent thoracic levels. The current is passed through two electrodes covering the nerve. The anatomic position of the medial branch in the thoracic spine is different from the cervical and lumbar spine, it is running more cranial and lateral over the transverse process. By making a bipolar RF lesion in this way the obtained lesion is larger than when only one electrode is used. The size of the lesion is defined by the space between the two electrodes, the size of the electrodes and the active tip and the RF lesion temperature.

This study is a factorial study aimed at evaluating the effect of bipolar RF treatment when studied in a larger group of patients. There is no control group.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1.Age 18-75 years

2.Almost continuous uni-or bilateral chronic pain in a circumscript thoracic spinal region without neurological signs

3.Uni- or bilateral paravertebral thoracic tenderness in the same region

4.On RX -spine normal or only minimal changes

5.Conservative therapy no or incomplete result

6.Having given informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1."Red Flags" like tumor, infection, fracture

2.Anticoagulation therapy, which may not temporarily be stopped

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Factorieel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2014
Aantal proefpersonen:	70
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	24-11-2013
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	NL4026
NTR-old	NTR4294
Ander register	13-N-130 : METC nummer
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A