A Randomized Controlled Trial to Evaluate the Efficacy of Pulsed Radiofrequency as a Treatment for Anterior Cutaneous Nerve Entrapment Syndrome in comparison to Anterior Neurectomy

Published: 19-08-2015
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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Peripheral neuropathies
Study type	Interventional

Summary

ID

NL-OMON42800

Source
ToetsingOnline

Brief title
Pulsed Radiofrequency vs Anterior Neurectomy in ACNES patients

Condition

- Peripheral neuropathies
- Nervous system, skull and spine therapeutic procedures

Synonym
ACNES, chronic abdominal-wall pain

Research involving
Human

Sponsors and support

Primary sponsor: Maxima Medisch Centrum
Source(s) of monetary or material Support: Financiering vanuit MMC zelf

Intervention

Keyword: ACNES, Chronic abdominal pain, Neurectomy, Pulsed Radiofrequency

Outcome measures

Primary outcome

Primary objective is to study the number of patients gaining at least 50% pain reduction within 8 weeks following PRF as compared to following a neurectomy.

Pain intensity will be measured using numeric pain rating score (NPRS, 0-10) and Verbal Rating Scales (VRS) methodology. Double measurement enables wider comparison of outcome to available literature. An Intention to Treat (ITT) principle is used.

Secondary outcome

A Number Needed to Treat (NNT) analysis at the 12-month time point for >=30% and >=50% pain relief using ITT principle.

Following secondary outcomes will be assessed at baseline, 8 weeks, 6 and 12 months:

• Evaluation characteristics of pain using The Douleur Neuropathique (DN4) questionnaire.

• Health related Quality of life improvements using Short Form-12 (SF-12) questionnaire.

• Pain disability improvements using Pain Disability Index (PDI).

• Patient satisfaction using Patient Global Impression of Change (PGIC)

questionnaire.

• Overall improvement measured using multidimensional Brief Pain Inventory

(BPI) questionnaire.

• Analgesic usage (Medication Usage of patients)

• There is a high concordance between pain and anxiety. State of anxiety

improvements and intergroup comparison will be measured using the State-Trait

Anxiety Inventory (STAI) .

Study description

Background summary

Anterior Cutaneous Nerve Entrapment Syndrome (ACNES) is caused by entrapment of end branches of intercostal nerves that are residing in the abdominal wall. Patients suffer from severe abdominal pain that is often not recognized as most doctors are focused, when confronted with abdominal pain, on a visceral source of the pain. If ACNES is diagnosed, treatment includes sub-fascial injections of an anestheticum (whether or not combined with an long acting corticosteroid). If pain is recurrent, the entrapped nerve is surgically removed. A neurectomy procedure is effective in approximately 70% of patients after one year. However, research on less invasive alternative treatment forms of ACNES is scarce.
Pulsed Radiofrequency (PRF) treatment is a relatively new form of treatment for chronic pain syndromes(1). Initial clinical studies were promising i.e. significantly reduced levels of chronic pain in a variety of pain syndromes. Therefore, it may be worthwhile to study PRF as an alternative approach for the treatment of ACNES.
This trial is aimed to evaluate the efficacy of PRF treatment and a neurectomy in subjects suffering from ACNES. If comparable, PRF may standard be included in the treatment plan as a less invasive alternative to the surgical procedure.

Study objective

Primary objective is to study the number of patients gaining at least 50% pain reduction within 8 weeks following PRF as compared to following a neurectomy. Pain intensity will be measured using numeric pain rating score (NPRS, 0-10)

and Verbal Rating Scales (VRS) methodology. Double measurement enables wider comparison of outcome to available literature. An Intention to Treat (ITT) principle is used.

Secondary Objectives

A Number Needed to Treat (NNT) analysis at the 12-month time point for >=30% and >=50% pain relief using ITT principle.
Following secondary outcomes will be assessed at baseline, 8 weeks, 6 and 12 months:
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• Pain disability improvements using Pain Disability Index (PDI).
• Patient satisfaction using Patient Global Impression of Change (PGIC) questionnaire.
• Overall improvement measured using multidimensional Brief Pain Inventory (BPI) questionnaire.
• Analgesic usage (Medication Usage of patients)
• There is a high concordance between pain and anxiety. State of anxiety improvements and intergroup comparison will be measured using the State-Trait Anxiety Inventory (STAI) .

Study design

The trial will be a multicentre, randomized (1:1 - PRF : neurectomy) controlled trial (RCT) with a one way optional crossover at 8 weeks to assess the efficacy of PRF as a form of treatment for ACNES in comparison with neurectomy. Subjects will be randomized to either arm of treatment, one arm being PRF and the other arm neurectomy treatment. Subjects will be followed for 6 months after receiving the procedure. At the 8 weeks follow up visit, the PRF group will be given the option to cross over to the alternate arm of the trial.
Either way, all are prospectively followed to 6 months evaluation time point, whether they have crossed over or not.

Intervention

Group 1 will recieve the Pulsed radiofrequency treatment, after which follow-up moments take place at 8 weeks, 6 and 12 months.
Group 2 will recieve the neurectomy surgery, after which follow-up moments take place at 8 weeks, 6 and 12 months.

In-Depth information about the Pulsed Radio Frequency can be found in the research protocol on page 19.

Study burden and risks

There are no additional risks to the subjects participating in this trial. When applied by ultrasound guidance, PRF treatment is a safe and standard treatment modality that is already being used at the Máxima Medical Centre for several other pain syndromes. It is already used in the Maasziekenhuis Pantein for treating patients with refractory ACNES following surgery.

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) Subject is diagnosed with unilateral ACNES
2) Eligible for neurectomy

3) Subject > 18 years old
4) Subject is able to provide written informed consent
5) Subject is willing to participate in the follow-up schedule and protocol

Exclusion criteria

1) Subject has surgical scar-related pain syndromes
2) Subject has recent intra-abdominal pathology.
3) Patient has other chronic pain syndromes (such as fibromyalgia, dystrophy, chronic low back pain)
4) Subject has other neuropathic diseases
5) Subject has impaired communication
6) Subject has participated in another clinical investigation within 30 days
7) Subject has had a spinal surgical procedure at or between vertebral levels T7-L1
8) Subject has been diagnosed with cancer in the past 2 years, except for skin malignancies
9) Female subject of childbearing potential is pregnant/nursing or plans to become pregnant during the course of the Trial
10) Significant anatomic deformity (either congenital or acquired)
11) Language barrier
12) Allergy to local anesthetics
13) Patient is not able to stop coagulantia

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-10-2015
Enrollment:	65

Type:	Actual

Ethics review

Approved WMO Date:	19-08-2015
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	13-07-2016
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 20554
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL53171.015.15
OMON	NL-OMON20554

Study results

Date completed:	31-01-2018
Actual enrolment:	66