Pulsed Radiofrequency in comparison to neurectomy in ACNES patiënts

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20554

Source
NTR

Brief title
PULSE Trial

Health condition

ACNES, anterior cutaneous nerve entrapment syndrome, abdominal wall pain, chronic abdominal pain

ACNES, buikwandpijn, chronische buikpijn

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 local anesthetic (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.

Sponsors and support

Primary sponsor: Maxima Medisch Centrum Veldhoven
Source(s) of monetary or material Support: Nvt

Intervention

Outcome measures

Primary outcome

Primary objective is to evaluate the effect of PRF treatment in comparison with neurectomy in terms of pain relief at 8 weeks follow up. This outcome will be measured using Numeric Pain Rating Scale 0-10 (0 = no pain and 10 = excruciating). Primary outcome will be the percentage of decrease on the NPRS scale.

Secondary outcome

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)

- State of anxiety improvements and intergroup comparison will be measured using the State-

Trait Anxiety Inventory (STAI) .

Study description

Study objective

Primary objective is to evaluate the effect of PRF treatment in comparison with neurectomy in terms of pain relief. This outcome will be measured using Numeric Pain Rating Scale 0-10 (0 = no pain and 10 = excruciating).

Hypothesis:

PRF as treatment for ACNES is equally effective (or better) than neurectomy

Study design

Baseline

8 weeks FU

6 months FU

12 months FU

Intervention

Subjects will be randomized to either arm of treatment, one arm being PRF and the other arm neurectomy treatment. Subjects will be followed for 12 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. All patients who do not cross over will be prospectively followed to 12 months evaluation time point.

Contacts

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Eligibility criteria

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) Patient has surgical scar-related pain syndromes

2) Patient has recent intra-abdominal pathology.

3) Patient has other chronic pain syndromes (such as fibromyalgia, dystrophy, chronic low back pain)

4) Patient has other neuropathic diseases

5) Patient has impaired communication

6) Patient has participated in another clinical investigation within 30 days

7) Patient has had a spinal surgical procedure at or between vertebral levels T7-L1

8) Patient has been diagnosed with cancer in the past 2 years, except for skin malignancies

9) Female patient 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 should be able to stop their anticoagulants

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2015
Enrollment:	65
Type:	Anticipated

Ethics review

Positive opinion
Date: 15-04-2015
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 42800
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4985
NTR-old	NTR5131
CCMO	NL53171.015.15
OMON	NL-OMON42800

Study results