Pulsed Radiofrequency in comparison to neurectomy in ACNES patiënts

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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:...

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

Samenvatting

ID

NL-OMON20554

Bron
NTR

Verkorte titel
PULSE Trial

Aandoening

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.

Ondersteuning

Primaire sponsor: Maxima Medisch Centrum Veldhoven

Overige ondersteuning: Nvt

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Doel van het onderzoek

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

Onderzoeksopzet

Baseline

8 weeks FU

6 months FU

12 months FU

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2015
Aantal proefpersonen:	65
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	15-04-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 42800
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten