The Anterior Cutaneous Nerve Entrapment Syndrome (ACNES). Retrograde transforaminal paresthesia mapping (RTPM) for patients with ACNES. A pilot study for the anatomical distribution of neuropathic pain in the trunk at the level of the dorsal root ganglion.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Peripheral neuropathies
Study type	Observational invasive

Summary

ID

NL-OMON42590

Source
ToetsingOnline

Brief title
ACNES-RETROMAP

Condition

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

Synonym
entrapped nerve abdominal wall, intercostal neuralgia

Research involving
Human

Sponsors and support

Primary sponsor: Maxima Medisch Centrum
Source(s) of monetary or material Support: vanuit de instelling (SolviMax;B.V. binnen Maxima Medisch Centrum)

Intervention

Keyword: ACNES, anatomic, dorsal root ganglion, mapping

Outcome measures

Primary outcome

The number of patients who confirm a one to one correlation between the

clinical suspected anatomical dermatome in which their ACNES pain point is

located and the corresponding dorsal root ganglion with RTPM

Secondary outcome

Electrophysiological aspects:

- If no one to one correlation is present, what is the mean number of DRG*s

involved.

- The relative contribution per DRG of elicited pain in the pain point in

percentages.

- Anatomical distribution of the elicited paresthesia using a drawing map

- The mean mV to illicit a pain response.

Differentiation between peripheral and central sensitized pain:

- The number of patients who report instantaneous complete remission of pain

caused by a procedure after local anaesthesia in the targeted DRG*s.

Pain reduction:

- Mean pain reduction on a Numeric Pain Rating Scale after PRF treatment

compared to baseline directly after treatment and 2 weeks and 6 weeks after

treatment.

- The percentage of patients with a >30% and >50% pain reduction on a NPRS.

Study description

Background summary

Anterior Cutaneous Nerve Entrapment Syndrome (ACNES) is a condition in which patients develop chronic neuropathic pain in the abdominal wall due to entrapped intercostal nerve terminals. The diagnosis is an old fashioned clinical one that is based upon the patient*s history and physical examination. It is usually confirmed by an injection with a local anesthetic agent into the so-called *pain point*: a point of maximal pain that is residing within the lateral edges of the rectus abdominis muscle. Such an abdominal wall injection is supposed to give a quick but often transient pain reduction if the diagnosis is valid.

However, sometimes this diagnostic injection gives inconclusive results (e.g. the pain is not responding although the diagnosis of ACNES is highly likely) . If so, a pain specialist performs an ultrasound or X-ray guided injection at multiple levels of the neural pathway of the intercostal nerve to assess at what level the pain arises, sometimes eventually blocking the nerve and establishing pain reduction at another level than the m. abdominis. The findings of this practice, combined with recent literature about the complex network of sensory innervation of the trunk and abdominal wall, confirmed the need for more extensive *pain mapping* of ACNES patients.

A promising technique possible allowing for a more focused approach is retrograde transforaminal paresthesia mapping (RTPM). This specific procedure is commonly performed as a precursor to (pulsed) Radio Frequency (pRF) ablation of the dorsal root ganglion (DRG) and as a predictor for the success of implantation of a spinal cord stimulation device.

Study objective

This mapping study will contribute to our understanding of the pathogenesis of ACNES and the complex anatomical distribution of sensory input of the trunk. It will also pave the way for a better diagnostic work-up, allowing for better surgical therapy results. Moreover, it could predict whether ACNES is a condition which can be treated with spinal cord stimulation techniques that are currently under trial in our center for patients with chronic neuropathic groin pain. Finally, it may be an alternative treatment option, since blocking or interference with the DRG using pRF may lead to pain relief.

Study design

Interventional pilot study.

Intervention

Retrograde transforaminal paresthesia mapping (RTPM) followed by pulsed radio frequency (pRF) treatment.

Study burden and risks

Possible: pain during the procedure (RTPM as well as pRF), pain in the back after the procedure, increase in pain intensity of the ACNES pain, transient loss of motor control in the legs and pneumothorax.

Description RTPM: The patient is positioned on his abdomen on the OR table. The back is sterilized. Three hollow needles are placed in the targeted dorsal root ganglia by the pain specialist using fluoroscopy. Then using short electrical stimulation the patient is asked to score the way in which each ganglion contributes to his painful spot on the abdominal wall. This is done for each DRG separately: in between stimulations there will be a pause of 3 minutes. Then the PRF procedure is started. The DRG's which contributed >10% to the painful spot are stimulated with an electrical current during 6 minutes, thus warming them to 42 degreees, what will positively influence the neural activity.

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

•Clinical diagnosis of ACNES:
•Localisation ACNES unilateral
•Clear, discrete pain point over the m. rectus abdominis
•Symptoms get worse upon flexing the abdominal muscles (Carnett*s sign positive)
•Good temporary effect of one local injection at the ACNES pain point with a local anesthetic.
;•Informed consent obtained and good apprehension of the procedure warranted
•Minimum age 18 years

Exclusion criteria

•Pregnancy
•Allergy or hypersensitivity to lidocaine
•Prior treatment for ACNES, such as peripheral nerve blocks, Pulsed-Radio-Frequency, epidural injections, etc.
•Adequate follow-up not warranted, for example because of mental retardation, dementia or a language barrier
•Spinal surgical procedures at or between vertebral levels Th8-L2 in medical history
•Known coagulation disorders or use of anticoagulants

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-08-2015
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	01-07-2015
Application type:	First submission
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

No registrations found.

In other registers

Register	ID
CCMO	NL52578.015.15