Nociceptive processing in anterior cutaneous nerve entrapment syndrome, a quantitative sensory testing analysis

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To investigate nociceptive processing and possible underlying pathological pain processing mechanisms in ACNES patients.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON38839

Source
ToetsingOnline

Brief title
Nociception in ACNES

Condition

- Other condition

Synonym
entrapped nerve in abdominal wall

Health condition

buikwand aandoening

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: ACNES, chronic abdominal wall pain, Nociception, QST

Outcome measures

Primary outcome

Pressure pain and electrical pain thresholds as investigated by QST.

Secondary outcome

Secondary study parameters are Visual Analog Scale (VAS) scores and results of

Pain Anxiety Symptom Scale (PASS) and Pain Catastrophizing Scale (PCS)

questionnaires.

Study description

Background summary

Chronic abdominal pain is a frequently occurring condition. Although hardly ever considered, the abdominal wall is the primary cause in 10-30% of cases. Most often it is caused by entrapment of an intercostal nerve in the anterior rectus sheath, the Anterior Cutaneous Nerve Entrapment Syndrome (ACNES). Treatment consists of local anaesthetic injections combined with methyl-prednisolon. When ineffective, a neurectomy at the site of penetration out of the ventral rectus sheet should be considered. This neurectomy however is effective in 73% of cases, leaving some 25% of patients in pain. Whether these refractory ACNES patients suffer from underlying pathologic pain disorders is subject to investigation, by using quantitative sensory testing (QST).

Study objective

To investigate nociceptive processing and possible underlying pathological pain processing mechanisms in ACNES patients.

Study design

An observational case-control study.

Study burden and risks

The patients participating will obtain no direct personal benefit. The results from the study will provide new insight into pain mechanisms and future treatment options for ACNES patients. There risks for the participants are negligible.

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. Patient has been diagnosed with abdominal complaints, matching ACNES:
i) Patient had a constant site of tenderness that is superficially located with a small (<2cm2) area of maximal tenderness.
ii) The most intense pain could be localized with the tip of one finger.
iii) Tenderness increased by abdominal muscle tensing (Carnett*s test).
2. has been treated (successfully and unsuccessfully) for ACNES.
3. Patient is at least 18 years old on the day the informed consent form will be signed.
4. Patient is willing and able to comply with the trial protocol.
5. Patient is able to speak, read and understand the local language of the investigational site, is familiar with the procedures of the study, and agrees to participate in the study program by giving oral and written informed consent prior to screening evaluations.

Exclusion criteria

1. Abdominal complaints were due to a condition other than ACNES (e.g. pain related to scar tissue).
2. Patient has (a history of) another (chronic) pain syndrome that interferes with the interpretation of QST results.
3. Patient has (a history of) a medical disorder that interferes with the study measurements or may pose a risk for the patient.
4. Patient does not feel a pinprick test to the lower extremities, due to affected sensory input (e.g. neuropathy as a result of diabetes mellitus).
5. Female patient is pregnant during the course of the study.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-06-2013
Enrollment:	70
Type:	Actual

Ethics review

Approved WMO

Date:	13-06-2013
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL43583.091.13