The anterior cutaneus nerve entrapment syndrome (ACNES). Randomized double blind controlled trial for the diagnosis and treatment of entrapment of the anterior cutaneus nerve through the rectus muscle.

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Evaluation of the effect ofdiagnostic and therapeutic proces in reducing pain in patients suspected with ACNES.Is injection of lidocaine in patients suspected of ACNES leading to a larger group of people with a clinically relevant reduction of pain...

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

Summary

ID

NL-OMON32058

Source
ToetsingOnline

Brief title
ACNES the diagnosis and treatment trial

Condition

- Peripheral neuropathies
- Skin and subcutaneous tissue therapeutic procedures

Synonym
abdominal wall nerve entrapment, ACNES

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Anterior cutaneus nerve, diagnosis, entrapment, treatment

Outcome measures

Primary outcome

The difference in number of patients with a clinically relevant reducion of

pain on VAS, 15 min after injection of Lidocain vs saline.

The difference in number of patients with a clinically relevant reducion of

pain on VAS after neurectomie vs sham operation.

A more than 50 % reduction on VAS is considered clinically relevant.

Secondary outcome

Fase 1, Diagnostic

* the difference in the number of people with longterm painfree result after

diagnostic injection (VAS<10)

* the absolute en relative difference on the VAS.

* difference on Verbal Rating Score (VRS)

Fase 2 en 3, therapie

* The number of patients pain free at 3 months after injection of lidocaine and

Kenacort

* Long term evaluation: frequency of patients developping a recurrent pain at

the site of surgery after a pain free period (VAS < 10) of at least 6 weeks

after neurectomy.

* Difference on the VRS

* difference in improvement on the SF-36

Study description

Background summary

Entrapment of one or more nerve branches in the rectus abdominis muscle , known as the anterior cutaneus nerve entrapment syndrome (ACNES), can cause abdominal pain and discomfort. It is often overseen as a cause of abdominal pain. Once diagnosed several therapeutic options are available. Our studiegroup propagates neurectomy, dissection of the nerve branches perforating the anterior fascia of the rectus abdominis muscle. In our own experience this leads to succesfully improving complaints in patients in about 75 % of the cases. Pain specialists and non-believers remain critical and doubt the surgical intervention to be usefull for various reasons.

Study objective

Evaluation of the effect ofdiagnostic and therapeutic proces in reducing pain in patients suspected with ACNES.

Is injection of lidocaine in patients suspected of ACNES leading to a larger group of people with a clinically relevant reduction of pain compaired to saline? Is neurectomy in patients suspected of ACNES leading to a larger group of people with a clinically relevant reduction of pain compaired to a 'sham' operation.

a 50 % reduction on the Visual Analouge Scale (VAS) is considered clinically relevant.

Study design

Double-blind randomised mono-centre trial devided in an diagnostic fase and a therapeutic fase.

Intervention

Fase 1, diagnostic: Injection of lidocaine vs saline at the painpoint
Fase 2, therapeutic conservative: injection of lidocaine and Kenacort at the painpoint in all patients
Fase 3, therapeutic operative: Neurectomy vs Sham operation.

Study burden and risks

The risk is cinsidered minor and no different than any procedure. Both infection and hematoma are the most common complications, alltough rare (less than 5 %), for injection and/or surgery. Sujested surgery is superficial and minor.

The biggest burden is on those subjected to a sham or placebo procedure. They potentially remain in pain for at least 6 weeks more. Eventually they will be offered a neurectomy at a later state. No longterm os irriversable hazzards are to be expected.

There is no personal benefit. This study will provide evidency of the entity ACNES and usefull treatment. More widespread knowlege of ACNES might prevent future patients to be submitted to unnecessary diagnostic procedures and even major abdominal surgery

Contacts

Public
Máxima Medisch Centrum

De Run 4600 Postbus 7777
5500 MB Veldhoven
Nederland
Scientific
Máxima Medisch Centrum

De Run 4600 Postbus 7777
5500 MB Veldhoven
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Localized abdominal wall pain in the rectus muscle
positive Carnett sign

Exclusion criteria

Suspected intra-abdominal pain
Anticoagulants use

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2008
Enrollment:	44

Type:	Actual

Ethics review

Approved WMO Date:	04-09-2008
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	NL23189.015.08