The Anterior Cutaneous Nerve Entrapment Syndrome (ACNES). Randomized controlled trial of conservative treatment by local injection therapy with or without use of ultrasound for entrapment of the anterior intercostal cutaneous nerve through the rectus abdominis muscle.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23723

Source
Nationaal Trial Register

Brief title
ACNES-ECHO

Health condition

Anterior Cutaneous Nerve Entrapment Syndrome (ACNES).

Sponsors and support

Primary sponsor: No sponsor
Source(s) of monetary or material Support: Not applicable

Intervention

Outcome measures

Primary outcome

The primary endpoint was the proportion of patients achieving at least 50 % reduction in pain perception measured on a Numeric Rating Scale (NRS) 15 minutes after the injection compared to directly before.

Secondary outcome

The secondary endpoints were the effect of the injection regimen on the long term (after 3 months) and the role of the location of the fluid depot (beneath muscle fascia or not).

Study description

Background summary

Abdominal pain has many causes. It often concerns intra-abdominal organs for which many diagnostic tests are available. However, the abdominal wall is often misunderstood as a cause of pain. Since the beginning of the last century, various authors have published about entrapment of the ramus cutaneus anterior of the intercostal nerve (Th 8-12) in the rectus abdominis muscle. Although various designations have recently appeared, mainly written about the Anterior (or Abdominal) Cutaneous Nerve Entrapment Syndrome (ACNES). A remarkable finding in this syndrome is that there is one clearly localized pain point, where the pain worsens when contracting of the abdominal muscles, the so-called sign of Carnett. This pain point is located exactly at the site of the passage of this nerve through the fascia of the rectus abdominis muscle.
If a diagnosis of ACNES is considered, it is recommended in the literature to confirm this by a diagnostic blockade using a local anesthetic around the nerve in question. f the patient indicates to be pain-free diagnosis can be considered proven.
Partly through our own research, which mainly consists of the publication of the retrospective data and two conducted double-blind randomized studies, it has now been conclusively demonstrated that this pain syndrome actually exists. One in three patients with ACNES can get pain reduction pain through an injection strategy, and it has been unambiguously demonstrated that it is the local anesthetic that works and not the volume bolus itself. Two out of three patients become permanently pain-free after a surgical neurectomy. However, many questions remain. One of those questions concerns the role of the use of ultrasound in the placement of the injection in the rectus fascia. No comparable data can be found in the literature. That is why we want to test this in a randomized study design.

Study objective

There is no difference in pain perception after 15-20 minutes between patients who received a local injection with the use of ultrasound versus a free hand technique.

Study design

Follow-up at 2, 4 and 6 weeks and after 3 months.

Intervention

Control: free hand lidocaine injection therapy
Intervention: ultrasound guided lidocain injection therapie

Contacts

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Eligibility criteria

Inclusion criteria

All adult patients (> 18 years) were eligible when suspected for an abdominal wall pain syndrome if all of the following criteria were met:
• Single tender point (trigger point);
• Constant site of abdominal tenderness with a small (< 2 cm) area of maximal intensity situated within the lateral boundaries of the rectus abdominis muscle;
• Tenderness increases by abdominal muscle tensing, using the Carnett’s test;

Exclusion criteria

Recent intra-abdominal pathology, lidocaine allergy, earlier treatment for ACNES, pregnancy and if adequate follow-up can’t be obtained. Informed consent was obtained if patient

characteristics fulfilled these criteria.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-01-2018
Enrollment:	190
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	18-03-2020
Application type:	First submission

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
NTR-new	NL8465
Other	METC Maxima Medisch Centrum : N16.171

Study results