

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.

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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.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23723

Bron

Nationaal Trial Register

Verkorte titel

ACNES-ECHO

Aandoening

Anterior Cutaneous Nerve Entrapment Syndrome (ACNES).

Ondersteuning

Primaire sponsor: No sponsor

Overige ondersteuning: Not applicable

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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. If 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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

Control: free hand lidocaine injection therapy

Intervention: ultrasound guided lidocain injection therapie

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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;

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	02-01-2018
Aantal proefpersonen:	190
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies	
Datum:	18-03-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8465
Ander register	METC Maxima Medisch Centrum : N16.171

Resultaten