

# The Anterior Cutaneus Nerve Entrapment Syndrome (ACNES). A 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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1. Lidocaine is a powerful tool in diagnosis; 2. Lidocaine with corticosteroids are beneficial in conservative treatment; 3. An anterior neurectomy is contributes to a substantial relief of pain in patients with failure of conservative treatment.

|                             |                       |
|-----------------------------|-----------------------|
| <b>Ethische beoordeling</b> | Positief advies       |
| <b>Status</b>               | Werving gestart       |
| <b>Type aandoening</b>      | -                     |
| <b>Onderzoekstype</b>       | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON26786

### Bron

Nationaal Trial Register

### Verkorte titel

ACNES diagnosis and treatment trial

### Aandoening

Abdominal wall pain

Anterior Cutaneus Nerve Entrapment

### Ondersteuning

**Primaire sponsor:** Performer: drs. O.B.A. Boelens

**Overige ondersteuning:** Initiator

# Onderzoeksproduct en/of interventie

## Uitkomstmaten

### Primaire uitkomstmaten

Fase 1: The difference in number of patients with a clinically relevant reduction of pain measured on VAS of at least 50 %, 15 minutes after infiltration of Lidocaine vs Saline.<br>Fase 3: The difference in number of patients with a clinically relevant reduction of pain measured on VAS of at least 50 %, 6 weeks after neurectomy vs sham.

## Toelichting onderzoek

### Achtergrond van het onderzoek

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

### Doel van het onderzoek

1. Lidocaine is a powerful tool in diagnosis;
2. Lidocaine with corticosteroids are beneficial in conservative treatment;
3. An anterior neurectomy is contributes to a substancial relief of pain in patients with failure of conservative treatment.

### Onderzoeksopzet

Fase 1: 15 minutes, 1 week;

Fase 2: 2 weeks;

Fase 3: 1 week, 6 weeks.

## Onderzoeksproduct en/of interventie

Fase 1, diagnosis: Patients will be randomized into two groups. One group will be infiltrated with 10 cc lidocaine at the triggerpoint, the control group will be infiltrated with 10cc of saline. Evaluation will follow at 15 minutes and at 1 week by short questionnaire and VAS.

Fase 2, conservative treatment: Following Fase 1 all patients from both groups will receive an injection with 40 mg of corticosteroids in 10cc of lidocaine in case the primary injection was not succesfull or only temporarily succesfull. Evaluation will follow at 15 minutes and 2 weeks by short questionnaire and VAS.

Fase 3, treatment: Patients are selected that had a positive result on one or more of the injections but only a temporary effect was achieved. These patients will be randomized into two groups. In one group an anterior neurectomy at the level of the ventral fascia of the rectus abdominal muscle will be performed via a small, 3-5 cm, transverse incision at the triggerpoint. In the control group a sham operation will be performed. Both procedures will be performed in daycare under general anesthesia. Evaluation will be performed at 1 week and 6 weeks. Incase no effect is achieved in the sham group a neurectomy is suggested and performed at patient's wishes. This will be decided on at least 6 weeks of follow-up

## Contactpersonen

### Publiek

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### Wetenschappelijk

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## Deelname eisen

### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Unilateral abdominal triggerpoint in rectus muscle;
2. More than 1 month continues pain;
3. Complaints worsen on physical activity;
4. Positive Carnett's sign.

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Age below 18 years;
2. Recent intra-abdominal pathology;
3. Proven lidocaine allergy;
4. Anticoagulants;
5. Coagulopathy;
6. No follow-up possible: mental retardation, dementia, impaired communication due to language.

## Onderzoekopzet

### Opzet

|                  |                       |
|------------------|-----------------------|
| Type:            | Interventie onderzoek |
| Onderzoeksmodel: | Parallel              |
| Toewijzing:      | Gerandomiseerd        |
| Blinding:        | Dubbelblind           |

Controle: Placebo

## Deelname

Nederland  
Status: Werving gestart  
(Verwachte) startdatum: 01-09-2009  
Aantal proefpersonen: 44  
Type: Verwachte startdatum

## Ethische beoordeling

Positief advies  
Datum: 30-09-2009  
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        | NL1900                              |
| NTR-old        | NTR2016                             |
| Ander register | METC/CCMO : 0818/NL23189.015.08     |
| ISRCTN         | ISRCTN wordt niet meer aangevraagd. |

## Resultaten