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.

Gepubliceerd: 30-09-2009 Laatst bijgewerkt: 18-08-2022

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.

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

Samenvatting

ID

NL-OMON26786

Bron
NTR

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.
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 cutaneus 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 abdomins 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

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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 fysiacal 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 communicatio due to language.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	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