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.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26786

Source
Nationaal Trial Register

Brief title
ACNES diagnosis and treatment trial

Health condition

Abdominal wall pain
Anterior Cutaneus Nerve Entrapment

Sponsors and support

Primary sponsor: Performer: drs. O.B.A. Boelens
Source(s) of monetary or material Support: Initiator

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

Fase 1: Difference in the number of patients with longterm painfree result after diagnostic injection (VAS<10); absolute and relative difference on VAS; Difference on Verbal Rating Scale.

Fase 2: the number of patients with a painfree result after infiltration with lidocain and corticosteroids at follow-up of hree months.

Fase 3: Longterm evaluation: frequncy of patients developing a recurrent pain at the site of surgery after a painfree period of at least 6 weeks.

Difference on Verbal Rating Scale.

Improvement on FS-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 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.

Study objective

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.

Study design

Fase 1: 15 minutes, 1 week;

Fase 2: 2 weeks;

Fase 3: 1 week, 6 weeks.

Intervention

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

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2009
Enrollment:	44
Type:	Anticipated

Ethics review

Positive opinion

Date:	30-09-2009
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	NL1900
NTR-old	NTR2016
Other	METC/CCMO : 0818/NL23189.015.08
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results