The Anterior Cutaneous Nerve Entrapment Syndrome (ACNES) 3.0 Randomized single-blind controlled trial of conservative treatment by local injection therapy (with or without corticosteroids) for entrapment of the anterior intercostal cutaneous nerve through the rectus abdominis muscle.

Published: 07-08-2013
Last updated: 24-04-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON39921

Source
ToetsingOnline

Brief title
ACNES-Cortico

Condition

- Other condition

Synonym
The Anterior Cutaneous Nerve Entrapment Syndrome (ACNES). Chronic abdominal wall pain

Health condition

buikwandpijnsyndroom

Research involving
Human

Sponsors and support

Primary sponsor: Maxima Medisch Centrum
Source(s) of monetary or material Support: geen geldstroom;eigen werk en inzet

Intervention

Keyword: ACNES, corticosteroid, lidocaine, pain score

Outcome measures

Primary outcome

Difference of number of patients with a more than 50% pain reduction on VAS

and/or a 2 point reduction on the 5-point VRS 2-3 weeks after the second

injection.

Secondary outcome

Pain levels 3 months after diagnosis and the necessity of other treatment for

ACNES during this period

Study description

Background summary

ACNES is the anterior cutaneous nerve entrapment syndrome, characterized by (chronic) abdominal wall pain caused by entrapment of the end branches of these intercostal nerves at the level of the rectus abdominis fascia.
One of the therapies is local injections with anesthetics sometimes combined with corticosteroids like 40 mg methylprednisolonacetate. From our own

retrospective data it seems advantageous to inject the combination. However, no randomized data exist on this subject and literature on other pain syndromes is controversial with reference to the use of corticosteroids locally.
Therefore we conduct this randomized trial

Study objective

The main question is: results addition of 40mg of corticosteroids to 10 cc lidocaine 2% for local trigger point injection in a significant pain reduction compared to 10 cc lidocaine 2% alone. Pain reduction is defined as more than 50% decrease on a VAS scale and/or 2 points reduction on a 5 points VRS (McGill) pain questionnaire.

Study design

Single blind randomized controlled two center study (Maxima MC Veldhoven and Maas Hospital Boxmeer)

Intervention

Group A: trigger point injection with10 cc lidocaine 2% combined with 40mg of corticosteroids 2-3 weeks after diagnosis and repeated once more 2-3 weeks later.

Group B (control): trigger point injection with 10 cc lidocaine 2% only 2-3 weeks after diagnosis and repeated once more 2-3 weeks later.

Study burden and risks

Since trigger point injection is normal standard treatment, there is no extra burden for these patients.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

-abdominal wall pain (ACNES)
-unilateral
-trigger point in musculus rectus
-worse with Carnett's test
-more than 50% pain reduction by local infiltration
-informed consent
-age over 18

Exclusion criteria

-recent abdominal pathology
-previous treatment for ACNES
-allergic to lidocaine or methylprednisolonacetaat
-no adequate follow up possible
-blood analysis abnormalities not compatible with ACNES

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-08-2013
Enrollment:	136
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Depo-Medrol
Generic name:	methylprednisolone
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Lidocain
Generic name:	Lidocain
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	07-08-2013
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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
EudraCT	EUCTR2013-002426-24-NL
Other	Nederlands trial register NTR2016
CCMO	NL41980.015.13