ACNES 3.0
Single-blind gerandomiseerde trial voor het
Anterior Cutaneous Nerve Entrapment Syndrome.
Resultaten van een injectieregime met of zonder corticosteroïden.

No registrations found.

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

Summary

ID

NL-OMON24284

Source
NTR

Brief title
ACNES-CORTICO

Health condition

Abdominal wall pain caused by entrapment of intercostal nerve branches at the level of the rectus abdominus muscle.
= ACNES

Sponsors and support

Primary sponsor: none
Source(s) of monetary or material Support: initiator

Intervention

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

Summary andBackground:

Entrapment of one or more of the branches of the cutaneous intercostal nerves Th8 – Th12, while they passage through the sheath of the musculus rectus abdominis may lead to an abdominal wall pain syndrome

This clinical entity is known as the Anterior Cutaneus Nerve Entrapment Syndrome (ACNES).

Our department has gained a lot of experience in diagnosing and treating patients with this: SolviMáx, Center of Excellence for Abdominal Wall and Groin Pain.

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.

Objective of the study:

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.
Endpoint of the study will be reached after 12 weeks.

Study objective

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.

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

Time path
Week
1 2-3 4-5 6-7 12
x-----x----------x----------x---------------------------------x
a b c d e

a = moment of diagnosis and diagnostic injection
b = 1ste therapeutic trial injection
c = 2de therapeutic trial injection
d = primary end point evaluation
e = secundary end point evaluation and deblinding

Intervention

Groep A: trigger point injection with 10 cc lidocaine 2% plus 40 mg methylprednisolonacetate 2-3 weeks after diagnosis and repeated after 2-3 weeks.

Groep B (controle): trigger point injection with only 10 cc lidocaine 2% weeks after diagnosis and repeated after 2-3 weeks.

Contacts

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Eligibility criteria

Inclusion criteria

Inclusion criteria:

• abdominal wall pain consistent with signs of ACNES

• Localisation unilateral

• one single pain trigger point within the borders of musculus rectus abdominis

• pain worse by Carnett sign

• good (temporary) effect of local anesthetic (more than 50% pain reduction) after one single injection with local anesthetic into or around triggerpoint

• Informed consent

• age above 18 years

Exclusion criteria

Exclusion criteria:

• recent other intra-abdominal pathology

• allergic to local anesthetic (lidocaïne) of corticosteroïds

• Previous treatment for ACNES, like by corticosteroïds, Pulsed-Radio-Frequency, epidural injections, etc.

• No adequate follow-up possible

• abnormal laboratory results possibly compatible with other i.a. pathology

• Patiënts with a (relative) contra-indication for the use of corticosteroïds: besides allergy, known with ulcus duodeni of ventriculi, with viral or fungal infections, tropical worm infections, recently vaccinated.

• Pregnancy

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2013
Enrollment:	136
Type:	Anticipated

Ethics review

Positive opinion

Date:	18-08-2013

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	NL3961
NTR-old	NTR4141
Other	NL 41980.015.12 : ABR NUMBER
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A