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

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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...

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

Samenvatting

ID

NL-OMON24284

Bron
NTR

Verkorte titel
ACNES-CORTICO

Aandoening

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

Ondersteuning

Primaire sponsor: none
Overige ondersteuning: initiator

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2013
Aantal proefpersonen:	136
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	18-08-2013
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	NL3961
NTR-old	NTR4141
Ander register	NL 41980.015.12 : ABR NUMBER
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A