

GroinPain Trial: the effect of a neurectomy compared with an injection with lidocain, corticosteroids and hyaluronic acid on postherniorrhaphy inguinodynia.

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The pain reductive effect of a neurectomy of the ilio-inguinal, ilio-hypogastric or/ and genital branch of the genito-femoral nerve(s) is significantly more compared to an injection with lidocain, corticosteroids and hyaluronic acid for neuropathic...

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

Samenvatting

ID

NL-OMON24923

Bron

NTR

Verkorte titel

N/A

Aandoening

Inguinal Pain

Ondersteuning

Primaire sponsor: Department of General Surgery, Maxima Medical Centre, Veldhoven

Overige ondersteuning: unfunded

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Change on pain score (Surgical Pain Scales and McGill Pain Questionnaire - Dutch Language Version).

Toelichting onderzoek

Achtergrond van het onderzoek

Chronic pain is a common complication after inguinal hernia repair (20-40%). In approximately 4% of patients, pain originates from entrapment or damage of the inguinal nerves. Previous retrospective research has showed surgical treatment, neurectomy, to be effective in 70-80% of these patients. However, current treatment by pain specialists comprises of injections with lidocain, corticosteroids and hyaluronic acid. To evaluate appropriate treatment for these neuropathic pain syndromes a randomised controlled trial was set up comparing these treatment modalities.

We expect the surgical treatment to be more effective in reducing pain than injections (max 3 injections using a neurostimulator with a two-week interval). After six months patients in the injection-group are offered a cross-over to the surgical group.

Statistical analysis: sample-size 2 groups of 27 patients, power 90%, type I error 0.05, intention-to-treat analysis.

Primary outcome measure: pain reduction (Surgical Pain Scales, McGill Pain questionnaire - Dutch language version), Secondary outcomes: 1. complications, 2. neurophysiological changes (LANNS), 3. Quality of life (SF-36 version II), 4. Change in employment status.

Doel van het onderzoek

The pain reductive effect of a neurectomy of the ilio-inguinal, ilio-hypogastric or/ and genital branch of the genito-femoral nerve(s) is significantly more compared to an injection with lidocain, corticosteroids and hyaluronic acid for neuropathic groin pain syndrome.

Onderzoeksproduct en/of interventie

Neurectomy of ilio-inguinal, ilio-hypogastric or/ and genital branch of the genito-femoral nerve(s) compared with an injection with lidocain, corticosteroids and hyaluronic acid on postherniorrhaphy inguinodynia.

Contactpersonen

Publiek

Maxima Medical Center, Department of Surgery, P.O. Box 7777
R.M.H. Roumen
De Run 4600
Veldhoven 5500 MB
The Netherlands
+31 (0)40 8888000

Wetenschappelijk

Maxima Medical Center, Department of Surgery, P.O. Box 7777
R.M.H. Roumen
De Run 4600
Veldhoven 5500 MB
The Netherlands
+31 (0)40 8888000

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Nerve entrapment or damage of ilio-inguinal, ilio-hypogastric or/ and genital branch of the genito;-femoral nerve(s) confirmed with peripheral nerve blockade with Lidocain;
2. Corrected inguinal hernia;
3. Inguinal pain > 3 months;
4. Age of 18 yrs or older;
5. Adequate follow-up possible.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Presence of inguinal hernia recurrence;
2. Local inguinal inflammatory signs;
3. Patient classified as American Society of Anaesthesiologist Class 3 or more.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blinding:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-02-2006
Aantal proefpersonen:	54
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	23-10-2006
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	NL801
NTR-old	NTR814

Register

Ander register
ISRCTN

ID

: N/A
ISRCTN93771787

Resultaten

Samenvatting resultaten

N/A