

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

<b>Submission date</b> 28/12/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 28/12/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 26/03/2021	<b>Condition category</b> Signs and Symptoms	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Dr R M H Roumen

### Contact details

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Department of Surgery  
P.O. Box 7777  
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5500 MB

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

## Study information

### Scientific Title

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

### Study objectives

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.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Approval received from the Medical Ethics Board Maxima Medical Centre on the 1st May 2006 (ref: 0543).

### Study design

Randomised, controlled, parallel group trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Not specified

### Study type(s)

Treatment

### Participant information sheet

### Health condition(s) or problem(s) studied

Inguinal Pain

### Interventions

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

### Intervention Type

Drug

### Phase

Not Specified

**Drug/device/biological/vaccine name(s)**

Lidocaine, corticosteroids and hyaluronic acid

**Primary outcome measure**

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

**Secondary outcome measures**

1. Complications
2. Alterations in inguinal neurophysiological status (Leeds Assessment of Neuropathic Symptoms and Signs [LANNS] pain scale)
3. Quality of life (Short Form health survey [SF-36] version II)
4. Change in employment status

**Overall study start date**

01/02/2006

**Completion date**

01/02/2008

## Eligibility

**Key inclusion criteria**

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 Lidocaine
2. Corrected inguinal hernia
3. Inguinal pain more than three months
4. Age of 18 yrs or older
5. Adequate follow-up possible

**Participant type(s)**

Patient

**Age group**

Not Specified

**Sex**

Not Specified

**Target number of participants**

54

**Total final enrolment**

54

**Key exclusion criteria**

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

**Date of first enrolment**

01/02/2006

**Date of final enrolment**

01/02/2008

## **Locations**

**Countries of recruitment**

Netherlands

**Study participating centre**

**Maxima Medical Center**

Veldhoven

Netherlands

5500 MB

## **Sponsor information**

**Organisation**

Maxima Medical Center (The Netherlands)

**Sponsor details**

Department of General Surgery

P.O. Box 7777

Veldhoven

Netherlands

5500 MB

**Sponsor type**

Hospital/treatment centre

**ROR**

<https://ror.org/02x6rcb77>

## **Funder(s)**

**Funder type**

Hospital/treatment centre

**Funder Name**

MÁxima Medical Center (The Netherlands)

# Results and Publications

## Publication and dissemination plan

Not provided at time of registration

## Intention to publish date

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		01/05/2018	26/03/2021	Yes	No