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

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
28/12/2006		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
28/12/2006	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
26/03/2021	Signs and Symptoms			

# 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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# Additional identifiers

**Protocol serial number** 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

#### Study type(s)

Treatment

### 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 inquinodynia.

#### Intervention Type

Drug

#### Phase

**Not Specified** 

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

Lidocaine, corticosteroids and hyaluronic acid

#### Primary outcome(s)

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

## Key secondary outcome(s))

- 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

#### 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 inquinal hernia
- 3. Inguinal pain more than three months
- 4. Age of 18 yrs or older
- 5. Adequate follow-up possible

#### Participant type(s)

**Patient** 

#### Healthy volunteers allowed

No

#### Age group

**Not Specified** 

#### Sex

**Not Specified** 

#### Total final enrolment

54

#### Key exclusion criteria

- 1. Presence of inquinal 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

# Sponsor information

## Organisation

Maxima Medical Center (The Netherlands)

#### **ROR**

https://ror.org/02x6rcb77

# Funder(s)

## Funder type

Hospital/treatment centre

#### Funder Name

MÁxima Medical Center (The Netherlands)

# **Results and Publications**

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?
Results article		01/05/2018	26/03/2021	Yes	No