ISRCTN93771787 https://doi.org/10.1186/ISRCTN93771787

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

Submission date
28/12/2006

Recruitment status
No longer recruiting

Registration date
28/12/2006

Overall study status
Completed

Last Edited
26/03/2021

Condition category
Signs and Symptoms

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
Maxima Medical Center
Department of Surgery
P.O. Box 7777
Veldhoven
Netherlands
5500 MB

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 inguinodynia.

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 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

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

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)

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