Spinal versus General Anaesthesia in Surgery for Inguinodynia: a Randomized Controlled Trial

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25028

Source
Nationaal Trial Register

Brief title
SPINAZIE trial

Health condition

Chronic inguinodynia

Sponsors and support

Primary sponsor: Máxima Medical Center Veldhoven/Eindhoven
Source(s) of monetary or material Support: Máxima Medical Center Veldhoven/Eindhoven

Intervention

Outcome measures

Primary outcome

Effect of type of anaesthesia on pain relief (using Numerical Rating Scale) after remedial surgery

Secondary outcome

Effect of type of anaesthesia on:

1. quality of life (using Short Form Health Survery-12)

2. patient satisfaction

3. differences in pain medication

4. direct and indirect medical costs

5. complication rate

Study description

Background summary

Background

Inguinodynia is a common complication following inguinal hernia repair, but may also be found after other types of (groin) surgery. If conservative treatments are to no avail, tailored remedial surgery may be considered. Remedial surgery includes a neurectomy and/or a (partial) meshectomy. Two retrospective studies in patients with chronic inguinodynia suggested that spinal anaesthesia is superior compared to general anaesthesia in terms of pain relief following these operations. This randomized controlled trial is designed to confirm the effect of the type of anaesthesia (spinal or general) on pain relief following remedial surgery for inguinodynia.

Methods

A total of 190 adult patients who suffer from unacceptable chronic (>3 months) inguinodynia, as subjectively judged by patients themselves, are included. Only patients scheduled to undergo remedial surgery including a neurectomy and/or a meshectomy by an open approach are considered for inclusion and randomized to spinal or general anaesthesia. Patients are excluded if pain is attributable to abdominal causes or if any contra-indications for either type of anaesthesia are present. Patients will be followed-up up to one year postoperatively. Primary outcome is the effect on the type of anaesthesia on pain relief. Secondary outcomes include patient satisfaction, quality of life, use of analgesics and (in)direct medical costs.

Study objective

Spinal anaesthesia is superior compared to general anaesthesia in terms of pain relief following remedial surgery for chronic groin pain.

Study design

Postoperative after 1 week, 6 weeks, 3 months (short term)

Postoperative after 6 months and 1 year

Intervention

spinal anaesthesia or general anaesthesia (during remedial surgery)

Contacts

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Eligibility criteria

Inclusion criteria

Patients aged >18 years suspected for a groin pain syndrome (based on patient history, physical examination and diagnostic injection (10cc lidocaine 1-2% with or without corticosteroids);

Persistent groin pain ≥3 months;
Unacceptable pain levels (subjective by patient) despite one or several injections with local anaesthetics or other conservative treatments;
Groin pain with origin in one of the three inguinal nerves or inserted mesh;
Neurectomy and/or meshectomy by an open approach;
Informed consent obtained.

Exclusion criteria

Groin pain caused by intercostal neuralgia (lower abdominal cutaneous nerve entrapment syndrome (ACNES));
Involvement of the lateral femoral cutaneous nerve;
Pregnancy;
Contra-indications for general or spinal anesthesia;
Indication for retroperitoneal neurectomy;
Cognitive impairment;
Malignancy;
Previous remedial surgery on same site in MMC;
Bilateral groin pain sugery;
ASA class >III;
Pre-existant neurological deficiency;
Inability to speak or understand the Dutch language.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-01-2016
Enrollment:	190

Type:	Anticipated

Ethics review

Positive opinion
Date: 15-01-2016

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 42411
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL4173
NTR-old	NTR5586
CCMO	NL54115.015.15
OMON	NL-OMON42411

Study results