Spinal versus General Anaesthesia in Surgery for Inguinodynia: a Randomized Controlled Trial (SPINAZIE trial)

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To assess the effect of the setting of two types of anaesthesia (spinal versus general anaesthesia) on outcomes of remedial surgery (i.e. quality of life, patient satisfaction and pain relief) in patients diagnosed with chronic inguinodynia.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON42411

Source
ToetsingOnline

Brief title
RCT Spinal versus General Anaesthesia for Groin Pain Surgery

Condition

- Other condition

Synonym
groin pain, inguinodynia

Health condition

pijn

Research involving
Human

Sponsors and support

Primary sponsor: Maxima Medisch Centrum
Source(s) of monetary or material Support: Financiering door RVE Stichting Máxima Medisch Centrum.

Intervention

Keyword: Anaesthesia, Groin pain surgery, Inguinodynia, Pain management

Outcome measures

Primary outcome

Primary outcome is the reduction of postoperative pain, patient satisfaction

and quality of life, on short (<3 months) and long term (up to 1 year).

Secondary outcome

Secondary outcome measures are differences between the setting of anaesthesia

regarding the origin of groin pain, types of remedial surgery, preoperative use

of analgesics, direct and indirect costs of the intervention and complication

rates.

Study description

Background summary

Patients suffering from persisting inguinodynia (following inguinal hernia repair, Pfannentiel incision or by other causes) may undergo remedial surgery after conservative treatments failed. Remedial surgery may consist of removal of inguinal nerves and/or mesh removal. SolviMáx is highly experienced with these surgical treatments. Two previously performed retrospective studies have demonstrated that the type of anaesthesia (spinal or general anaesthesia) is associated with the outcome of remedial surgery. However, this potential association has never been investigated in a prospective, randomized setting.

Study objective

To assess the effect of the setting of two types of anaesthesia (spinal versus

general anaesthesia) on outcomes of remedial surgery (i.e. quality of life, patient satisfaction and pain relief) in patients diagnosed with chronic inguinodynia.

Study design

Randomized controlled trial.

Intervention

Patients are randomized between spinal and general anaesthesia. The conventional protocols are used for the types of anaesthesia.

Study burden and risks

All procedures will be executed following the conventional protocols, with execption of the randomization of the type of anaesthesia (general or spinal anaesthesia). Therefore, no additional risks are associated with participation in the present study. Burden for patients include completing six questionnaires regarding quality of life, pain scores, satisfaction, use of analgesics, medical consumption, work productivity and complications (preoperative and 1 week, 6 weeks, 3 months, 6 months and 12 months postoperative).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

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);
- Persisting 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
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-01-2016
Enrollment:	190
Type:	Actual

Ethics review

Approved WMO

Date:	04-12-2015
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 25028
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL54115.015.15
Other	volgt
OMON	NL-OMON25028