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

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25028

Bron
Nationaal Trial Register

Verkorte titel
SPINAZIE trial

Aandoening

Chronic inguinodynia

Ondersteuning

Primaire sponsor: Máxima Medical Center Veldhoven/Eindhoven
Overige ondersteuning: Máxima Medical Center Veldhoven/Eindhoven

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

surgery

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Postoperative after 6 months and 1 year

Onderzoeksproduct en/of interventie

spinal anaesthesia or general anaesthesia (during remedial surgery)

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	13-01-2016
Aantal proefpersonen:	190
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	15-01-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 42411
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten