Optimal anesthesia in hallux valgus surgery:
A prospective randomized controlled trial comparing popliteal nerve block versus combined spinal and local infiltration anesthesia

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To assess whether patients receiving simple hallux valgus surgery ambulate independently earlier after spinal anesthesia combined with LIA, compared to popliteal blocks. We hypothesize that both groups will demonstrate sufficient pain relief.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)
Study type	Interventional

Summary

ID

NL-OMON46291

Source
ToetsingOnline

Brief title
Optimal anesthesia in hallux valgus surgery

Condition

- Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)

Synonym
anesthesia in bunion surgery

Research involving
Human

Sponsors and support

Primary sponsor: Canisius Wilhelmina Ziekenhuis
Source(s) of monetary or material Support: Canisius Wilhelmina Ziekenhuis;Jonkerbosch Medisch Specialistisch Bedrijf Nijmegen

Intervention

Keyword: anesthesia, hallux valgus, mobility, surgery

Outcome measures

Primary outcome

Time to ambulate independently after surgery. Independent ambulation is defined

by the ability to walk without the assistance of another person or crutches.

Secondary outcome

1. Post-operative pain as indicated by the patient. NRS pain was collected at

standard times: return to ward, and at 7.00, 12.00, 17.00, 22.00.

2. Patient satisfaction was surveyed using a paper questionnaire prior to

discharge the next day.

Study description

Background summary

Hallux valgus correction is a common orthopaedic procedure and suitable for day surgery (Maher 2009, Mouton 2015). Adequate pain relief and early mobilization are important, but the optimal peri- and postoperative anesthesia technique to accommodate outpatient hallux valgus surgery remains a challenge (Adam 2012). Locoregional blocks have proven to cause durable anesthesia, depending on type of anesthetic used (Grosser 2007, Kullenberg 2006). However, a prolonged time of analgesia also results in prolonged absence of motor control impeding independent ambulation (Adam 2012). Spinal anesthesia is quick and reliable, but may not give enough pain relief in the first 24 hrs post-surgery (Clough

2003). Local infiltration anesthesia (LIA) has successfully decreased post-operative pain in total knee arthroplasty, facilitating early mobilization and reducing the need for additional oral analgesics. In hallux valgus surgery, the local field block has shown to be an efficacious LIA technique (Gerbert 1996, Adam 2012). It involves infiltration of local anesthetic through all tissues proximal to the surgical site in a ring block fashion. There is limited evidence that shows that LIA can cause durable anesthesia and facilitate safe early mobilization in day care percutaneous hallux valgus surgery (Adam 2012). Although prolonging the time to first perceived pain, local foot blocks do not necessarily improve patient satisfaction in the outpatient setting (Clough 2003).
Here, we compare the popliteal nerve block versus combined spinal and local infiltration anesthesia in a prospective randomized controlled trial. Early mobility, pain relief and patient satisfaction after hallux valgus surgery were assessed in a short stay clinicial setting.

Study objective

To assess whether patients receiving simple hallux valgus surgery ambulate independently earlier after spinal anesthesia combined with LIA, compared to popliteal blocks. We hypothesize that both groups will demonstrate sufficient pain relief.

Study design

Clinical randomized controlled prospective trial in a short-stay setting

Intervention

Popliteal anesthesia versus a combination of spinal anesthesia and local infiltration anesthesia.

Study burden and risks

Patient burden is limited to a paper questionnaire.
There are no benefits for participating patients.
Risks are limited to standard procedure related risks depending on anesthesia technique in both groups.

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

- Indication for Chevron ± Akin technique
- Age 18 * 75 yr
- ASA I * II

Exclusion criteria

- Standard contraindications for hallux valgus surgery
- Impaired mobility due to other causes than hallux valgus.
- Previous surgery on the ipsilateral foot.
- Spinal malformation.
- Patients demanding general anesthesia or day care surgery
- Patients using pain medication prior to surgery.
- Inability to understand or correctly interpret the questionnaire (mental retardation, language barrier)

Study design

Design

Study phase:	4
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):	01-09-2018
Enrollment:	60
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Articaine HCl
Generic name:	Articaine HCl
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	Ropivacaine HCl
Generic name:	Ropivacaine HCl
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	19-03-2018
Application type:	First submission

Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2017-001441-27-NL
CCMO	NL61454.091.17