Hyperbaric Prilocaine 2% for spinal anesthesia 60 or 80 mg: a dosing study in day care patients.

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To obtain a time effect curve of prilocaine 2% hyperbaric for intrathecal use in day case surgery

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

Summary

ID

NL-OMON47932

Source
ToetsingOnline

Brief title
Hyperbaric Prilocaine 2% for spinal anesthesia.

Condition

- Other condition

Synonym
back injection, spinal anesthesia

Health condition

lokaal anesthesie tbv operatieve ingrepen in dagbehandeling

Research involving
Human

Sponsors and support

Primary sponsor: anesthesiologie
Source(s) of monetary or material Support: Nordicpharma,vakgroepinitiatief;geen extra financiering nodig;anders dan eigen inzet anesthesiologen en arts-assistenten.

Intervention

Keyword: anesthesia, hyperbaric, prilocaine, spinal

Outcome measures

Primary outcome

Maximum block height (sensibility and motor) Time of regression to T10, L1 and

S2 (sensibility)

Time of regression of motor block

Time to spontaneous urination or catherization

Secondary outcome

the amount of fluid infused during and after surgery and the amount of fluids

taken postoperatively

bladder volume pre and postoperatively and at discharge if the patient did not

urinate yet

time of first urine production. If the patient does not urinate during

admission, he/she will be asked to record the time at home

bladder catheterization if necessary and volume additional analgesics per and

postoperatively use of vasopressors

patient satisfaction with the procedure

time of discharge, night admission if necessary and reason for night admission

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Study description

Background summary

Until recently no short acting spinal local anesthetic was registered in the Netherlands. Older anesthetics such as articaine were not reregistered by their manufacturers. Short acting spinal local anesthetics are important in our practice for day case surgery. Up till now we used articaine based on dutch legislation enabling use if no registered medication is available.
Recently prilocaine 2% hyperbaric (prilotekal ®) was registered in the Netherlands for intrathecal use. We plan to switch to prilotekal. Manufacturers dosing advice is 60 mg with a maximum of 80 mg. However there is only limited and controversial literature with regard to dosing. For arthroscopy of the knee dosages of 20 mg with 20 microgram fentanyl up to 60 mg were used with good results. For bilateral open inguinal hernia repair a dosage of 50 mg was sufficient, although the level of anesthesia did not extend above the level of the ninth dermatome. These findings are not in line with our limited experience. In our practice bilateral open inguinal hernia repair is a challenging operation in day case surgery. A high anesthetic level up to the fourth thoracic dermatome is needed for the duration of the surgery. If this is not achieved manipulation of the peritoneum will be painful. Spinal anesthesia is most intense and long lasting in the lumboscral segments and will rise to thoracic levels where it will be short lasting. Our experience with 80 mg so far is just acceptable. This may be due to longer operation times and a different technique as suggested in a recent review. This review also notices that little data are available with regard to anesthetic spread in the elderly. High dosages will reduce failure rated and reduce the use of rescue medication or general anesthesia. However lower doses reduce the severity and duration of adverse effects of spinal anesthesia such as hypotension, bradycardia and high thoracic block extending above the required level. Low doses will also promote early discharge.
Instead of a trial and error method to find the right dose in our practice we aim to perform a proper dose effect study.

Study objective

To obtain a time effect curve of prilocaine 2% hyperbaric for intrathecal use in day case surgery

Study design

Patients will receive 60 or 80 mg. Block randomisation in blocks of 20 will be

used. Only the anesthetist performing the spinal anesthetic will know the dosage. Patient and observer are blinded. A copy of the randomisation list is available in the OR in case of an emergency. If the attending anesthesiologist has important medical reasons to administer a different dose this will be recorded. This decision has to be made before randomisation

For every patient these data will be recorded:

height of the anesthetic block (sensibility and motor) every 5 minutes up till incision. As far as possible during surgery every 15 minutes
height of the anesthetic block (sensibility and motor) on arrival in the recovery room and then every 15 minutes
height of the anesthetic block (sensibility and motor) on the ward every 30 minutes until discharge or complete resolution of block
amount of fluids ingested up till 6 hours before surgery
the amount of fluid infused during and after surgery and the amount of fluids taken postoperatively
bladder volume pre and postoperatively and at discharge if the patient did not urinate yet
time of first urine production. If the patient does not urinate during admission, he/she will be asked to record the time at home
bladder catheterisation if necessary and volume
additional analgesics per and postoperatively
use of vasopressors
patient satisfaction with the procedure
time of discharge, night admission if necessary and reason for night admission

Intervention

Use of 60 mg or 80 mg prilocaine 2% hyperbaric for lower limb surgery

Study burden and risks

Patients do get the same anesthetic as they would have had except the dose is fixed in advance. They will only have more tests for block height (sensibility for ice), motor response and measurement of bladder volume with ultrasound. The risks are thus the same as for patients outside the study.

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 requiring spinal anesthesia for lower limb surgery in day case surgery.

Exclusion criteria

age younger than 18 yrs
pregnancy
allergy for prilocaine or other amide type local anesthetics
hereditary or acquired methaemoglobinaemia
severe heart conduction abnormalities *
severe anaemia *
unstable cardiac failure *
hypovolemic, cardiogenic or other forms of circulatory shock *

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-05-2016
Enrollment:	100
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	prilotekal
Generic name:	prilocaine 2% hyperbaric
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	10-02-2016
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	18-02-2016

Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	21-02-2017
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	08-02-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	25-01-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	09-12-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	EUCTR2015-000882-29-NL
CCMO	NL52509.098.15