Chloroprocaine vs prilocaine for spinal anaesthesia in day-case surgery: a double-blind randomized trial

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To investigate effectiveness of spinal chloroprocaine, and prilocaine in day case surgery. The null hypothesis is that there is no significant intergroup difference in complete recovery from motor blockade.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Nervous system, skull and spine therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON44965

Source
ToetsingOnline

Brief title
SPACE (SPinal Anesthetics Chloroprocaine prilocainE)

Condition

- Nervous system, skull and spine therapeutic procedures

Synonym
spinal anaesthesia

Research involving
Human

Sponsors and support

Primary sponsor: Zaans Medisch Centrum
Source(s) of monetary or material Support: Het onderzoek wordt gefinancieerd uit eigen middelen van het ZMC

Intervention

Keyword: chloroprocaine, prilocaine, spinal anaesthesia

Outcome measures

Primary outcome

The time to complete motor block recovery

Secondary outcome

Urine retention needing catheterisation and Transient Neurologic Syndrom

(TNS).

Study description

Background summary

In day-case surgery, spinal anaesthesia with both rapid onset and a short duration of block is preferred. For this purpose, lidocaine has been the drug of choice for decades but has been associated with an unacceptable number (20-30%) of transient neurologic symptoms (TNSs). In recent years, chloroprocaine (CP) and prilocaine (P) have gained interest as short-acting spinal anaesthetics seemingly without the issue of urinary retention or TNSs. So far, these drugs have not been compared as to whether one would be more preferable than the other in an ambulant setting.

Study objective

To investigate effectiveness of spinal chloroprocaine, and prilocaine in day case surgery. The null hypothesis is that there is no significant intergroup difference in complete recovery from motor blockade.

Study design

A double-blind randomized controlled trial

Intervention

Patients receive intrathecally 40 mg plain chloroprocaine or 40 mg hyperbaric prilocaine.

Study burden and risks

Physical examinations are the main burden for the patients participating in this trial. Both sensory and the motor block are followed as usual but with a higher frequency before, during and after the knee arthroscopy. Concerning the sensory block, ice cubes are used at 2,4,6,8,10, 15, 20, 25 and 30 min, and then at 15-min intervals until the sensory blockade had regressed tot dermatome S2. Motor blockade is evaluated at 5, 10, 15, 20, 25, 30, 45, 60, 75 and 90 min and then every 15 min until both legs can be fully elevated.
The urinary bladder will be examined by ultra-sound 30 min postoperative.
On the first and seventh post-operative days, the patients are interviewed by telephone for any possible adverse events and their satisfaction as to their spinal anaesthesia.
No blood samples will be taken.

There is no expected benefit for an individual trial participant. We hope that our findings will benefit future patients in a similar situation.

The risk for an individual trial participant is expected to be very low because the trial
drugs are licensed for the purpose we will use them for. Furthermore, spinal anaesthesia with
prilocaine in knee arthroscopy is standard care in the Zaans Medical Centre.

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

- Scheduled ambulatory knee arthroscopy
- Age >18 years
- ASA physical status I- II

Exclusion criteria

- Allergy to one of the study drugs
- Contraindication to neuraxial anaesthesia
- Previous neuropathy to the lower extremities
- Pregnancy

Study design

Design

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):	25-11-2016
Enrollment:	150
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Ampres
Generic name:	chloroprocaine
Product type:	Medicine
Brand name:	Prilotekal
Generic name:	prilocaine
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	29-02-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-07-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-03-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-04-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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: 26258
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
EudraCT	EUCTR2015-001944-13-NL
CCMO	NL53492.029.15
OMON	NL-OMON26258

Study results

Date completed: 15-06-2018

Results posted: 09-09-2019

Actual enrolment: 151

First publication
26-08-2019