ED90 of intrathecal 1% chloroprocaine in day-case knee arthroscopy: a Biased-Coin-Up-and-Down sequential allocation trial

Published: 10-01-2018
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To determine the effective dose ED90 of Chloroprocaine for patients undergoing knee arthroscopy.

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

Summary

ID

NL-OMON47564

Source
ToetsingOnline

Brief title
CORONA

Condition

- Nervous system, skull and spine therapeutic procedures

Synonym
spinal anaesthesia

Research involving
Human

Sponsors and support

Primary sponsor: VUMC
Source(s) of monetary or material Support: Gerrit Blaauw Fonds,Het onderzoek wordt

gefinancieerd uit eigen middelen van het ZMC;Maasstad;VUMC en een subsidie van Gerrit Blaauw Fonds

Intervention

Keyword: chloroprocaine, knee arthroscopy, spinal

Outcome measures

Primary outcome

Successful anesthesia. Anesthesia is considered successful when:

1. Complete loss of cold sensation at the L2 dermatome, AND

2. Pain is 0-2 following inflation of the tourniquet and zero upon incision

3. Pain is 0-3 during surgery

Secondary outcome

Motor block

TNS (Transient Neurologic Syndrom)

Urine retention

Patient satisfaction

Study description

Background summary

In day case lower limb surgery, spinal anaesthesia with both rapid onset and a short duration of block is preferable. A short acting spinal anaesthetic facilitates a smooth patient flow: quick recovery of motor function will facilitate unassisted ambulation.
In the Netherlands chloroprocaine is expected to be licensed in 2017. From that point, chloroprocaine and prilocaine will be the only two short acting anaesthetics with a license for spinal administration in the Netherlands. So far, the optimal dose of chloroprocaine has not been clinically established for ambulatory knee arthroscopy regarding quick postoperative mobilization and patient comfort.

Study objective

To determine the effective dose ED90 of Chloroprocaine for patients undergoing knee arthroscopy.

Study design

prospective double blind

Intervention

In the first part of the study, the injected dose op CP will be varied according to the a Biased-Coin-Up-and-Down sequential allocation
The dose of CP that a patient receives is determined by the previous patient*s response. If successful anesthesia was obtained, the next patient*s dose will be the same or decreased with 5 mg. Conversely, if anesthesia was not successful, the next patient*s dose is the same of increased with 5 mg. In the second part of the study, all patients receive the ED90 dose determined in the first part. This observational section is performed with a chosen sample of patients scheduled for the same type of surgery.

Study burden and risks

The risk for an individual trial participant is expected to be very low because the trial
drug is licensed for the purpose we will use it for. However, as a consequence of the study design there will be a number of patients with an insufficient block. To prevent unnecessary pain or discomfort for the patient, start- and stopcriteria for the study procedure are defined. For occurrences of inadequate analgesia, patients will receive additional analgetics.

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-III

Exclusion criteria

Allergy to chloroprocaine;
Contraindication to neuraxial anaesthesia;
Allergy to local anesthetics of the ester-type: cocaine, oxybuprocaine, procaine, tetracaine.
Allergy to parabens or paraaminobenzoic-acid (PABA)
Pseudocholinesterase deficiency
Previous neuropathy to the lower extremities;
Pregnancy;

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	09-07-2018
Enrollment:	90
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Ampres
Generic name:	chloroprocaine

Ethics review

Approved WMO Date:	10-01-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-03-2018
Application type:	First submission
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

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2017-002559-27-NL
CCMO	NL61905.029.17

Study results

Date completed: 19-02-2021

Results posted: 02-11-2022

First publication
28-12-2021