

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

Published: 10-01-2018

Last updated: 04-01-2025

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

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Completed
<b>Health condition type</b>	Nervous system, skull and spine therapeutic procedures
<b>Study type</b>	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

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

## Intervention

**Keyword:** chlorprocaine, 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 chlorprocaine is expected to be licensed in 2017. From that point, chlorprocaine 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 chlorprocaine 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 of 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 or 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

### Public

VUMC

De Boelenlaan 1117  
Amsterdam 1081 HV  
NL

### Scientific

VUMC

De Boelenlaan 1117  
Amsterdam 1081 HV

## 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**

EudraCT

CCMO

**ID**

EUCTR2017-002559-27-NL

NL61905.029.17

## Study results

Date completed: 19-02-2021

Results posted: 02-11-2022

**First publication**

28-12-2021