Optimale dosering voor een ruggenprik bij kortdurende operaties.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23383

Source
NTR

Brief title
CORONA

Health condition

Spinal anesthesia for knee arthroscopy

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

Succesfull 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

- Urine retention

- Patient satisfaction

Study description

Background summary

In day-case surgery, spinal anesthesia with both rapid onset, a short duration of block and minimal side effects is preferred. Chloroprocaine (CP) is increasingly used for this purpose. 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

We will establish the optimal dose chloroprocaine for knee-arthroscopy

Study design

Sensibel block at t=2, 4, 6, 8, 10, 15, 20, 25, 30 until end of recovery

Motor block at t=5, 10, 15, 20, 25, 30, 45, 60

Pain score at inflation of the tourniquet and during surgery

Intervention

• In the first part of the study, the injected dose of chloroprocaine will be varied according to the modified up-and-down sequential allocation method (UDM) established by Dixon and Massey.14,15 The dose of chloroprocaine that a patient receives is determined by the previous patient’s response. If successful anesthesia was obtained, the next dose will be decreased. Conversely, if anesthesia was not successful, the next dose is increased. Treatment allocation will take place one day before hospital admission.

• 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.

Contacts

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Eligibility criteria

Inclusion criteria

• Scheduled elective ambulatory knee arthroscopy

• Age >18 years

• American Society of Anesthesiology physical status I- III

Exclusion criteria

• Allergy to one of the trial drugs

• Contraindication to neuraxial anesthesia

• Previous neuropathy to the lower extremities

• Pregnancy

• No informed consent

Study design

Design

Study type:	Interventional
Intervention model:	Factorial
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-02-2018
Enrollment:	90
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	16-11-2017
Application type:	First submission

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
NTR-new	NL6769
NTR-old	NTR6946
Other	VUMC : 2018.026

Study results