The effect of intravenous fluid preload on diuresis during spinal anesthesia-induced detrusor blockade

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Objective: to compare the quantitative effects of Ringer Lactate and HES 6% on diuresis during spinal anesthesia-induced detrusor blockade as well as prevention of hypotension and vasopressor use.

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON30651

Source
ToetsingOnline

Brief title
Preload and diuresis during spinal anesthesia

Condition

- Other condition

Synonym
diuresis, urine production

Health condition

perioperatieve anesthesiologische zorg

Research involving
Human

Sponsors and support

Primary sponsor: Rijnstate Ziekenhuis
Source(s) of monetary or material Support: Geen financiering

Intervention

Keyword: detrusor blockade, diuresis, preload, spinal anesthesia

Outcome measures

Primary outcome

Primary outcome is total urinary volume during spinal induced detrusor

blockade, and number of subjects that have a bladdder volume over 500ml.

Secondary outcome

Secondary outcome parameters:

Periods of hypertension, and total dose of vasopressor en extra fluid

administration.

Study description

Background summary

Spinal anesthesia , through interruption of spinal nerve conduction, causes intense blockade of sensation, motor function as well as (para)sympathetic function. Loss of sympathetic tone causes vasodilation which may lead to arterial hypotension and bradycardia. To avoid these effects, in anesthetic practice, usually intravenouspreload is administered as cristalloids or colloids. The form and dosage of these plasma expanders will influence diuresis during spinal anesthesia-induced detrusor blockade. Excess diuresis may cause bladder distension and neccecitates bladder catheterization

Study objective

Objective: to compare the quantitative effects of Ringer Lactate and HES 6% on diuresis during spinal anesthesia-induced detrusor blockade as well as prevention of hypotension and vasopressor use.

Study design

Before spinal anesthesia is performed, patients are randomized into one of the 3 study groups (no preload, preload with Ringers' Lactate 14 ml/kg, preload with HES 6% 7 ml/kg). Spinal anesthesia is administerd with lidocaine 2% 70mg. Hypotension is treated with vasopressors, atropine or additional intravenous fluid. Bladder scans will be performed on the recovery unit and day-case unit. Total urinary volume is measured until sensory function at dermatome S2/3 is restored and spontanous voiding is possible.

Intervention

Prespinal administration of intravenous Ringers' Lactate 14 ml/kg or HES 6% 7 ml/kg.

Study burden and risks

Except for extra bladderscan and block height measurements, all actions are part of routine anesthesiologic care.

Contacts

Public
Rijnstate Ziekenhuis

Wagnerlaan 55
Arnhem
Nederland
Scientific
Rijnstate Ziekenhuis

Wagnerlaan 55
Arnhem
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

patients planned for short, minor surgery of lower extremity under spinal anesthesia.

Exclusion criteria

any urologic, neurologic, cardiac, vascular disease.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2007
Enrollment:	150
Type:	Anticipated

Medical products/devices used

Product type:	Medicine

Brand name:	HemoHes 6%
Generic name:	HemoHes 6%
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	13-07-2007
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	EUCTR2007-000702-71-NL
CCMO	NL11881.091.07