Hemodynamic assessment during spinal anesthesia using transthoracic echocardiography

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON44596

Source
ToetsingOnline

Brief title
Spinal Anesthesia and Transthoracic Echocardiography (SATE)

Condition

- Other condition

Synonym
hypotension, low blood pressure

Health condition

effecten van anesthesiologische handelingen

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Echocardiography, Spinal Anesthesia, transthoracic (TTE)

Outcome measures

Primary outcome

effect of spinal anesthesia on vena cava inferior collapsibility, and

interrater variability of transthoracic ultrasound assessment of vena cava

inferior diameter and collapsibility

Secondary outcome

correlation between vena cava inferior collapsibility and peroperative

hypotension

Study description

Background summary

Spinal anesthesia is a safe, frequently used anesthetic technique. The main side effect of spinal anesthesia is hypotension, occuring in up to 85 % of selected cases. This hypotension is often treated with fluid infusion. However, especially in elderly patients, high volume fluid infusion can lead to fluid overload.
The effects of spinal anesthesia on preload and fluid responsibility are not exactly known. Hence, therapy for hypotension after spinal anesthesia might not be adequate. With transthoracic echocardiography, vena cava inferior diameter and collapsibility can be used to monitor fluid responsiveness and guide fluid management.

Study objective

The objective of this study is to explore the effects of spinal anesthesia on hemodynamic parameters of fluid status, especially vena cava inferior diameter

and collapsibility. T
Furthermore, the correlation between vena cava inferior collapsibility and the occurence and degree of hypotension after spinal anesthesia will be explroed.

Study design

Observational pilot study

Study burden and risks

The burden of this study will be the performance of multiple transthoracic echocardiography exams. No medication will be given and no other intervention will take place. No changes in anaesthetic practice will occur upon entering the study.

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

- Adult age (>18 years)
- Written informed consent
- Minor surgery under the umbilicus, e.g. herniorapphy, transurethral resection of bladder or prostate, orthopaedic procedures
- ASA class I or II

Exclusion criteria

- No informed consent
- ASA class III or higher
- Obstetric surgery
- Emergency procedures
- Pre-existing neurological injury or disease
- Contra-indications for spinal anesthesia (e.g. coagulation abnormalities)

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	26-01-2015
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	03-10-2014
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	27-07-2016
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
ClinicalTrials.gov	NCT02315937
CCMO	NL50108.060.14