Blood pressure regulation during spinal anesthesia in patients with diabetes mellitus type 2

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What is the incidence of a blood pressure decrease of more than 20% after spinal anesthesia in patients with diabetes mellitus type II in comparison with non-diabetics?

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Diabetic complications
Study type	Observational non invasive

Summary

ID

NL-OMON34285

Source
ToetsingOnline

Brief title
Spinal-BP

Condition

- Diabetic complications

Synonym
Diabetes mellitus, hyperglycemia

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Autonomic function, Blood pressure regulation, Diabetes mellitus type 2, Locoregional analgesia

Outcome measures

Primary outcome

Preoperative heart rate variability and arterial blood pressure changes during

spinal anesthesia in patients with and without diabetes mellitus.

Secondary outcome

Autonomic function, heart rate and blood pressure response as measured by heart

rate variability, forced breathing and the cold pressure test

Study description

Background summary

Spinal anesthesia is a form of regional anesthesia involving injection of a local anesthetic into the subarachnoid space. Spinal anesthesia causes somewhat similar effects as intravenous *1- and *-adrenergic blockers, including decreased heart rate and arterial pressure. Although these hemodynamic changes may occur more frequently in patients with diabetes mellitus II due to cardiovascular and autonomic nervous system disorders, there are only limited data available with respect to the specific effects of diabetes on blood pressure control during spinal anesthesia. In the present study we aim to evaluate whether patients with diabetes develop a relatively stronger blood pressure drop after spinal anesthesia in comparison with non-diabetics. In particular, we will investigate whether preoperative information about heart rate variability may be used as predictor for intraoperative blood pressure drops after spinal anesthesia.

Study objective

What is the incidence of a blood pressure decrease of more than 20% after spinal anesthesia in patients with diabetes mellitus type II in comparison with non-diabetics?

Study design

Open, prospective observational multicenter study

Study burden and risks

Non-invasive beat-to-beat blood pressure monitoring: All included subjects receive a finger cuff to measure arterial blood pressure. This cuff may in some cases lead to local cyanosis in the finger, but this is not experienced as discomfortable. Assessment of autonomic function: All included subjects undergo non-invasive cardiovascular reflex tests in the hour before surgery that will not add up to patient discomfort.

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

Age between 18*85 years
Elective surgery with spinal anesthesia
Informed consent

Exclusion criteria

Refusal of spinal anesthesia
Caesarean section
Pregnancy
Peripheral vascular disease
Renal disease requiring hemodialysis or peritoneal dialysis
Diabetes mellitus I

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-01-2011
Enrollment:	136
Type:	Actual

Ethics review

Approved WMO

Date:	01-11-2010

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
CCMO	NL33491.029.10