Diabetic cardiovascular autonomic neuropathy, a silent risk factor for general anesthesia and outcome; prevalence, diagnostics and perioperative care

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Answering the following questions:1. Are simple autonomic function tests using continuous blood pressure measurements useful to diagnose CAN at the preoperative screening? a. Are simple autonomic function tests using continuous blood pressure...

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

Summary

ID

NL-OMON33612

Source
ToetsingOnline

Brief title
CAN study

Condition

- Other condition
- Diabetic complications

Synonym
Diabetes Mellitus

Health condition

algehele anesthesie

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Anesthesia, Cardiovascular autonomic neuropathy, Diabetes, Risk factors

Outcome measures

Primary outcome

* Consistency in the results of the autonomic function tests at the outpatient

preoperative screening clinic and the official autonomic function test

laboratory.

* The correlation between CAN and intra- and postoperative hemodynamic- and

autonomic instability

Secondary outcome

* The prevalence of CAN in patients with diabetes at the preoperative

outpatient screening clinic diagnosed by analysis of patient files.

* Demographic patient variables: age, sex, weight, length, comorbidities.

Study description

Background summary

A serious complication of diabetes mellitus is cardiovascular autonomic neuropathy (CAN), which is associated with disturbed regulation of blood pressure, heart rate and coronary blood flow. CAN may be a perioperative risk factor for myocardial infarctions but is difficult to diagnose. Furthermore, preoperative assessment of cardiac risk remains challenging because reliable

and objective clinical parameters are currently lacking. We therefore aim to define preoperative parameters which predict intraoperative and postoperative risks.

Study objective

Answering the following questions:

1. Are simple autonomic function tests using continuous blood pressure measurements useful to diagnose CAN at the preoperative screening?

a. Are simple autonomic function tests using continuous blood pressure measurements at the preoperative screening valid to diagnose CAN and consistent over time?
b. Are preoperative symptoms of CAN as measured in the preoperative screening outpatient clinic related to peri-operative hemodynamic- and autonomic instability?
c. What is the prevalence of patients diagnosed with CAN in diabetic patients, who visited the preoperative outpatient screening clinic?

Study design

Open, prospective, clinical study with non-invasive measurements

Study burden and risks

In general, the burden and risks associated with the present study are minimal due to its non-invasive character. The non-invasive autonomic neuropathy measurements, which play a central role in this investigation, will be performed preoperative and postoperative.
We will perform the following (cardiovascular reflex) tests:
* Classical Ewing tests (Parasympathetic function: heart rate response to deep breathing, Valsalva ratio, heart rate changes during standing. Sympathetic function: sustained handgrip test, systolic blood pressure response to standing)
* Measures of heart rate variability (HRV)
* Determination of Qtc intervals
The tests will only be performed when patients are comfortable with this tests which are not related to any kind of discomfort. The remaining part of the study will be performed by research in the status or anesthetic chart of the participants. In total, the burden associated with the present study is considered as minimal. There are no benefits associated with participation.

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

* Diabetes mellitus, type II
* Age between 40*75 years
* Scheduled for surgery
* Informed consent

Exclusion criteria

* Known/documented cardiac disease
* Use of medication for hypertension
* Abnormal ECG or echocardiogram
* Peripheral vascular disease

* Renal disease requiring hemo- or peritoneal dialysis

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):	01-06-2009
Enrollment:	96
Type:	Actual

Ethics review

Approved WMO

Date:	02-04-2009
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	NL26318.029.08