QUANtification of Cardiovascular Autonomic Neuropathy (CAN) and the effects of anaesthesia on hemodynamics and cerebral perfusion

Published: 08-06-2016
Last updated: 20-04-2024

1) To study whether peri-operative haemodynamics fluctuate more in patients with DM2 and CAN. 2) To study whether CAN further worsens cerebral perfusion in addition to impaired CA.

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

Summary

ID

NL-OMON46328

Source
ToetsingOnline

Brief title
QUANCAN Study

Condition

- Diabetic complications

Synonym
Autonomic neuropathy as a result of diabetes, cardiovascular autonomic neuropathy

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Autonomic neuropathy, Brain perfusion, Diabetes

Outcome measures

Primary outcome

Between group difference in hemodynamic parameters and cerebral perfusion parameters.

Secondary outcome

Determine the relationship between autonomic function tests and clinical outcome during 30-postoperative days (observational). Outcome measures include frequency of all adverse and serious adverse events.

Study description

Background summary

Complications of chronic hyperglycaemia associated with Diabetes Mellitus type 2 (DM2) include macro- and microvascular angiopathy. Cerebral Autoregulation (CA), the capability of the brain to maintain constant cerebral blood flow (CBF) despite changes in blood pressure, is impaired early in DM2 implicating that CBF becomes dependent on blood pressure. In addition, 20-60% of all patients with DM2 suffers from cardiovascular autonomic neuropathy (CAN) resulting in more unstable blood pressure regulation. In patients without DM2 or CAN, induction of anaesthesia results in slightly decreased blood pressure, but cerebral perfusion is maintained through CA. In contrast, patients with DM2 and CAN may display greater reductions in blood pressure and cerebral perfusion may become jeopardized due to impaired CA. This could be an explanation for the increased incidence of stroke in patients with DM2.

Study objective

1) To study whether peri-operative haemodynamics fluctuate more in patients with DM2 and CAN.
2) To study whether CAN further worsens cerebral perfusion in addition to impaired CA.

Study design

Prospective, observational cohort trial.

Observations:
1. PRE-operative: chart review, short physical examination, autonomic function tests to determine the presence of CAN. These tests are simple physiological tests that can be performed on a regular ward and involve a Vasalva manoeuvre, 3 minute paced breathing with a frequency of 6·min-1 and tests for orthostatic hypotension. Also, we test the sensitivity of the cerebral vasculature to CO2 by measuring during one-minute hyperventilation and one minute CO2-rebreathing. Continuous blood pressure monitoring will be obtained using ccNexfin, a non-invasive monitor that comprises a single inflatable finger cuff. Cerebral perfusion will be assessed non-invasively using transcranial Doppler attached with a headband to the temporal skin area.
2. INTRA-operative: we repeat the 3 minute paced breathing test and the CO2-reactivity test.
3. POST-operative: file revision and phone call to the research patient to detect complications 30 days postoperatively.

Study burden and risks

The study has no additional risks or benefits for the individual patient. All measurement methods are non-invasive and can be performed on a regular ward. All physiological tests are designed to test counterregulatory (homeostatic) reactions to stimuli within the physiological range. Therefore, we deem it appropriate not to give a financial compensation for participation in the study.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Willing and able to give written informed consent, scheduled for elective, non-cardiothoracic surgery under general anesthesia and age 18 years and above

Exclusion criteria

Day case surgery, laparoscopic procedure, DM type 1, Parkinson*s disease, uncontrolled cardiac arrhythmia, Pure autonomic failure (formerly called idiopathic orthostatic hypotension), Multiple system atrophy with autonomic failure (formerly called Shy-Drager syndrome), Addison*s disease and hypopituitarism, pheochromocytoma, peripheral autonomic neuropathy (e.g., amyloid neuropathy, idiopathic autonomic neuropathy), known cardiomyopathy, extreme left ventricle hypertrophy or ejection fraction < 30%, proven or suspected allergy for any of the medication used during induction of anaesthesia, malignant hyperthermia, unability to record transcranial doppler ultrasound due to anatomical variance.

Study design

Design

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

Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-08-2016
Enrollment:	45
Type:	Actual

Ethics review

Approved WMO Date:	08-06-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-09-2016
Application type:	Amendment
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	NL56806.018.16