DANS study - diabetic autonomic neuropathy in patients undergoing surgery

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON21686

Source
NTR

Brief title
DANS

Health condition

cardiovascular autonomic neuropathy
Diabetes mellitus
Surgery

Sponsors and support

Primary sponsor: Academic medical Centre, Department of Anaesthesiology
Source(s) of monetary or material Support: no funding

Intervention

Outcome measures

Primary outcome

- The prevalence of CAN in this surgical population

- The relation between the stage of CAN and hemodynamic changes*

* Hemodynamic changes are defined as:
- Postinduction hypotension: mean arterial pressure <55 mmHg measured within first 10 minutes after start induction.
- Postinduction mean arterial pressure; lowest mean blood pressure measured within first 10 minutes after start induction.
- Postinduction blood pressure change: difference between highest mean arterial pressure before induction and lowest after induction before intubation.
- Postinduction heart rate change: difference between minimum heart rate after induction and maximum heart rate before induction.
- Maximum heart rate during tracheal intubation.
- Maximum mean arterial blood pressure during tracheal intubation.
- Perioperative inotropics; definition: total dose of inotropics (mcg/kg/hour) during surgery. Maximal dose during surgery (mcg/kg/hour)
- Perioperative hypotension: mean arterial pressure < 55 mmHg at any time during the procedure.
- Postoperative inotropics; definition: total dose (mcg/kg/hour) of inotropics after surgery.

Secondary outcome

- Ejection fraction postoperative compared to preoperatively in patients undergoing cardiac surgery, (pre- and postoperative transthoracic/transesophageal ultrasound images are made for standard care).
- Mean glucose during surgery, glucose increase during surgery, hyperglycaemia (>10 mmol/l) during surgery (measured for standard care).
- Plasma creatinine difference before and day 0, 1 and 2 after surgery (when measured for standard care).
- Length of ICU and/or in-hospital stay
- Length of inotropic dependent hours after surgery
- In-hospital mortality < 30 days after surgery
- Duration of DM
- Presence of other DM related complications
o Peripheral neuropathy (assessed with the Semmes-Weinstein test and tuning fork)
o Presence of micro-albuminuria (from treating physician)
o Retinopathy (based on last visit to ophthalmologist)
- Relation between DM related complications and stage of CAN

Study description

Background summary

Diabetes mellitus (DM) is associated with a two- to threefold increase in perioperative cardiovascular morbidity and mortality, compared to patients without DM. In addition to well-

known complications of DM, diabetic autonomic neuropathy may contribute to the perioperative cardiovascular morbidity and mortality. Cardiovascular autonomic neuropathy (CAN) is one of the most serious forms of diabetic autonomic neuropathy. Patients with CAN are at increased risk of perioperative hemodynamic instability, cardiopulmonary arrest, (postoperative) silent myocardial infarction and postoperative mortality.
There are different tests to determine CAN. Ewing's battery of tests are simple, inexpensive and reliable bedside tests for CAN. If these bedside tests can help us to predict perioperative cardiovascular instability in patients with DM, it might be important to assess patients with DM for the presence of CAN during their preoperative screening, for more vigilant perioperative management.
Objective:
1) What is the prevalence of CAN in patients with DM scheduled for major abdominal / cardiothoracic surgery?
2) Does the severity of CAN relate to perioperative hemodynamic changes?

Study objective

patients with diabetic cardiovascular autonomic neuropathy are more prone to hypotension during surgery and therefore require more inotropic/vaspressor medication perioperatively

Study design

Day before surgery: autonomic function tests
Day of surgery: standardized induction. Collection of perioperative data via chart review
Days after surgery: collection of postoperative data via chart review

Intervention

On the day before surgery, patients will be subjected to 5 non-invasive tests to assess diabetic CAN, there will be no invasive test performed for study purposes.

Contacts

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Eligibility criteria

Inclusion criteria

• Willing and able to give written informed consent

• (DM type 1 or type 2)

• Scheduled for major gastro-intestinal- or cardiothoracic surgery

• Age 18-85 years

• Sinus rhythm

Exclusion criteria

• Parkinson’s disease

• 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 hypertophy21

• Ejection fraction < 30%21

• Proven or suspected allergy for any of the medication used during induction of anaesthesia

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2014
Enrollment:	90
Type:	Actual

Ethics review

Positive opinion

Date:	24-11-2014
Application type:	First submission

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
NTR-new	NL4706
NTR-old	NTR4976
Other	NL49521.018.14 : 2014-242

Study results