DANS study - diabetic autonomic neuropathy in patients undergoing surgery

Gepubliceerd: 24-11-2014 Laatst bijgewerkt: 13-12-2022

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

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON21686

Bron
NTR

Verkorte titel
DANS

Aandoening

cardiovascular autonomic neuropathy
Diabetes mellitus
Surgery

Ondersteuning

Primaire sponsor: Academic medical Centre, Department of Anaesthesiology
Overige ondersteuning: no funding

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- 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.

Toelichting onderzoek

Achtergrond van het onderzoek

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?

Doel van het onderzoek

patients with diabetic cardiovascular autonomic neuropathy are more prone to hypotension

during surgery and therefore require more inotropic/vaspressor medication perioperatively

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• 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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-10-2014
Aantal proefpersonen:	90
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	24-11-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4706
NTR-old	NTR4976
Ander register	NL49521.018.14 : 2014-242

Resultaten