COMPAS studie

Gepubliceerd: 17-12-2014 Laatst bijgewerkt: 18-08-2022

continuous glucose monitoring in the perioperative period improves glycaemic control in patients with diabetes

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24618

Bron
NTR

Verkorte titel
COMPAS

Aandoening

diabetes mellitus
perioperative period
continuous glucose sensor

Ondersteuning

Primaire sponsor: Academic Medical Centre, university of amsterdam
Overige ondersteuning: No funding was received for this study. Edwards supplied the sensors with 50% discount.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The difference in median glucose 1 hour after surgery will be calculated as a measure of glycaemic control during surgery.

Furthermore, the difference in proportion of time spent in the target range, time spent above the target range and time spent below the target range between groups will be calculated.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Although hyperglycaemia in patients with diabetes mellitus (DM) is associated with complications after surgery, the frequency of glucose measurements in the perioperative period (during and after surgery) is notoriously low. In the general surgical population with DM, a postoperative glucose reduction of 1 mmol/l significantly decreases the occurrence of postoperative complications, implicating the necessity of glucose monitoring in the perioperative period. Over the past decade, several continuous glucose monitors (CGM) have been tested in the perioperative phase, but none has been deemed accurate enough without the need for placing a central venous line.

If we can accurately monitor glucose continuously during the perioperative period, this might improve glycaemic control, and thereby possibly reduce postoperative complications. Our objectives are to evaluate whether CGM improves glycaemic control.

Objective:

1. Does CGM improve glycaemic control in the perioperative period?

Doel van het onderzoek

continuous glucose monitoring in the perioperative period improves glycaemic control in patients with diabetes

Onderzoeksopzet

trial starts day of surgery

end of sensor period: three days after surgery

assessment of postoperative complications: 30 days after surgery

Onderzoeksproduct en/of interventie

use of continuous glucose sensor in the perioperative period

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Aged 18-85

- Able to give written informed consent

- Laparotomy or cardiac surgery with planned postoperative stay at PACU or Will receive an arterial line for standard patient care

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Any condition that the local investigator feels would interfere with trial participation or the evaluation of results

- Allergy for heparin

- Known HIT

- Total pancreatectomy

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2015
Aantal proefpersonen:	36
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	17-12-2014
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	NL4764
NTR-old	NTR5009
Ander register	NL48359.018.14 : 2014_266

Resultaten