COMPAS studie

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24618

Source
NTR

Brief title
COMPAS

Health condition

diabetes mellitus
perioperative period
continuous glucose sensor

Sponsors and support

Primary sponsor: Academic Medical Centre, university of amsterdam
Source(s) of monetary or material Support: No funding was received for this study. Edwards supplied the sensors with 50% discount.

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

The secondary outcome measure include the accuracy of the GCM, measured by the mean absolute relative difference (MARD= (CGM value−POC/POC)).

Furthermore a Clarke error grid and Bland-Altman analyses, MARD in the lower glycaemic (glucose < 5 mmol/l), euglycaemic (glucose between 5 and 10 mmol/l) and hyperglycaemic (glucose >10 mmol/l) ranges. The ranges are according to the AMC protocol. The MARD during cardiopulmonary bypass and during the use of vasopressors will also be calculated. We will record the number of false alarms, the number of times the intravenous line has to be replaced due to failure of the device or clotting error.
Also, the glucose variability, the amount of insulin used and the occurrence hypoglycaemic events (glucose < 4.0 mmol/l) and severe hypoglycaemia (glucose <2.3 mmol/l) will be compared between groups. Glucose variability will be expressed as mean absolute glucose change (MAG) per hour18. The difference in occurrence of postoperative complications will be assessed according to Dindo-Clavien grading system19 30 days after surgery.

Study description

Background summary

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?

Study objective

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

Study design

trial starts day of surgery

end of sensor period: three days after surgery

assessment of postoperative complications: 30 days after surgery

Intervention

use of continuous glucose sensor in the perioperative period

Contacts

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Eligibility criteria

Inclusion criteria

- 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

Exclusion criteria

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

- Allergy for heparin

- Known HIT

- Total pancreatectomy

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2015
Enrollment:	36
Type:	Anticipated

Ethics review

Positive opinion

Date:	17-12-2014
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	NL4764
NTR-old	NTR5009
Other	NL48359.018.14 : 2014_266

Study results