The effect of continuous glucose monitoring on glycaemic control in patients undergoing major surgery

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Observational invasive

Summary

ID

NL-OMON40722

Source
ToetsingOnline

Brief title
COMPAS

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
glucose monitoring, sensor

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Glucose, Monitoring, perioperative, Sensor

Outcome measures

Primary outcome

The primary outcome measure is the difference in median glucose 1 hour after surgery, as a measure of glycaemic control during surgery.

Furthermore, the time spent in the target range, time spent above the target range and time spent below the target range will be calculated.

Secondary outcome

Secondary outcome measures include the accuracy of the GCM, measured by the mean absolute relative difference (MARD= (CGM value*POC/POC)). Furthermore, 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 hour17. The difference in occurrence of postoperative complications will be assessed 30 days after

surgery.

Study description

Background summary

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 reducing postoperative complications.

Study objective

Our objectives are to evaluate whether CGM improves perioperative glycaemic control.

Study design

This is an investigator-initiated randomized controlled trial. After informed consent, patients will be randomized on the day of surgery into two groups; the Standard Care (SC) arm and the Continuous Glucose (CG) arm.
* SC arm: the screen of the CGM (Edwards, GlucoClear) will be turned off during the perioperative period, but the glucose values will be registered. During the whole perioperative period, glucose is measured according to standard care: the AMC protocol (appendix 1) with a POC blood gas analyser (Siemens RAPIDlab 1265) and these values are used for guiding treatment. On the ward, glucose is measured and treated according to standard care. The CGM will be removed on day 2 after surgery. The POC values will be matched with the corresponding CGM values afterwards.
* CG arm: perioperative, a continuous glucose value will be visible on the screen and will guide treatment. When a perioperative value of the CGM is outside the target range, this will be double checked with the POC blood gas analyser. When glucose is below < 4 mmol/l, the POC value will be used to guide treatment. When glucose is > 10 mmol/l and the deviation is < 1 mmol/l we will use the GCM to guide teatment. If the deviation is > 1 mmol/l we will use the POC value to guide treatment. In addition, in these patients glucose will be

measured every 60-120 min during surgery with a POC blood gas analyser as a safety check. Postoperatively, only POC blood gas samples taken for standard care (every 60-120 min) will be matched with the values of the CGM. At 08.00 hr on day 1 postoperative, the screen of the CGM will be turned off. On the ward, glucose is measured and treated according to standard care. The CGM will be removed on day 3 after surgery. The POC values will be matched with the corresponding CGM value afterwards.
Thirty days postoperatively, the occurrence of postoperative complications will be established in all patients by a short telephone interview.

Study burden and risks

Potential risks
The only additional risk involved with this study is a thrombopheblitis in the vein where the monitoring device is inserted. This risk is small en easily treated.
Potential benefits
Glucose will be intensively monitored during surgery, which could improve the glucose regulation and decrease the risk of hypoglycaemia during surgery.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Aged 18-85
- Diagnosed with diabetes mellitus
- Able to give written informed consent
- Planned for laparotomy or cardiac surgery
- Will receive arterial line for standard patient care
- Planned postoperative stay at PACU or ICU

Exclusion criteria

- Any condition that the local investigator feels would interfere with trial participation or the evaluation of results
- Allergy for heparin
- Known heparin induced thrombocytopenia
- Planned total panceatectomy

Study design

Design

Study type:	Observational invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	02-01-2015
Enrollment:	36
Type:	Actual

Medical products/devices used

Generic name:	continuous glucose monitoring device
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	18-11-2014
Application type:	First submission
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	NL48359.018.14