Perioperative hyperglycaemia and glucose variability during major abdominal surgery

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In this study we want to investigate whether hyperglycaemia and blood glucose variability independently predicts postoperative complications in patients undergoing major abdominal surgery.

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

Summary

ID

NL-OMON35746

Source
ToetsingOnline

Brief title
PAVAS

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
stress hyperglycaemia

Research involving
Human

Sponsors and support

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

Intervention

Keyword: abdominal surgery, blood glucose variability, hyperglycaemia

Outcome measures

Primary outcome

Our main endpoint is the relation between postoperative complications and

hyperglycaemia and glucose variability.

Secondary outcome

Secondary endpoint is the difference in glucose increase and variability

between different surgical procedures and treating specialties.

Study description

Background summary

There is a considerable proportion of surgical patients that will develop hyperglycaemia during hospital admission, which will resolve spontaneously after hospital discharge, also called stress hyperglycaemia. When considering intra-operative hyperglycaemia, evidence is mounting that perioperative hyperglycaemia is related to postoperative complications after major surgery. Recently, it has been shown that glucose variability in combination with hyperglycaemia further contributes to this risk, which was in line with a previous study in the ICU, where increased glucose variability was associated with ICU mortality.
Currently, there are no trials that have evaluated the application and efficacy of perioperative glucose control in a non-ICU setting to target hyperglycaemia or glucose variability.
Randomized controlled trials are needed in this area, but first we have to identify which patient groups are at risk for perioperative hyperglycemia and glucose variability, as we know that not all patient groups show the association between hyperglycaemia and postoperative complications

Study objective

In this study we want to investigate whether hyperglycaemia and blood glucose variability independently predicts postoperative complications in patients

undergoing major abdominal surgery.

Study design

This is a single center prospective observational cohort study.

Study burden and risks

There are no risks associated with this study. A potential benefit may be the detection of undiagnosed diabetes mellitus. In general, after completion of this study the importance of hyperglycaemia and glucose variability during major abdominal surgery is investigated. This is a final and necessary step before a randomized controlled intervention trial treating intraoperative hyperglycaemia is considered.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
1100 DD Amsterdam
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
1100 DD Amsterdam
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- Willing and able to give written informed consent
- Scheduled to undergo major abdominal surgery
- Age 18-85 years

Exclusion criteria

- Early termination of the procedure
- Conditions necessitating prolonged stay (beyond the first postoperative day) at the recovery room, readmission to the recovery room, or admission to an intensive or medium care unit

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-11-2011
Enrollment:	400
Type:	Actual

Ethics review

Approved WMO

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	NL37308.018.11