Hyperglycaemia and Ambulatory Anaesthesia

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In this study we want to prospectively investigate in a large ambulatory surgical cohort in which patients glucose levels increase during surgery and whether this is related to postoperative complications.

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

Summary

ID

NL-OMON35862

Source ToetsingOnline

Brief title H2A

Condition

• Glucose metabolism disorders (incl diabetes mellitus)

Synonym stresshyperglycemie

Research involving Human

Sponsors and support

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

Intervention

Keyword: ambulatory anesthesia, hyperglycaemia, perioperative

Outcome measures

Primary outcome

Primary endpoints will be mean glucose change during ambulant surgery as compared to presurgery fasting glucose, proportion patients reaching a glucose value of * 7.8 mmol/l during admission, association between patients with glucose of * 7.8 mmol and seeking any medical help within the first 30 days after discharge.

Secondary outcome

Secondary endpoints will include mean change in glucose during surgery analyzed

with specific tests; predictive regression model for perioperative

hyperglycaemia; and the association between glucose change and any complication

within the first 60 days after discharge.

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. Evidence with regard to glucose control in patients undergoing ambulant surgery is scarce, whereas they constitute the largest surgical population that might be at risk for in-hospital hyperglycaemia.

Study objective

In this study we want to prospectively investigate in a large ambulatory surgical cohort in which patients glucose levels increase during surgery and whether this is related to postoperative complications.

Study design

multicentre prospective observatiobnal cohort study

Study burden and risks

The only additional risk involved with this study is an infection at the fingerstick injection site. This risk is small en easily treated. Potential benefits include finding undiagnosed diabetes mellitus. A patient has the right to withdraw from the study at any time. Reasons for dropouts, if available, will be documented.

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 for ambulant surgery
- * Age 18-85 years

Exclusion criteria

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

Study design

Design

Study type: Observational invasive		
Masking:	Open (masking not used)	
Control:	Uncontrolled	
Primary purpose:	Diagnostic	

Recruitment

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NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	07-10-2011
Enrollment:	1000
Туре:	Actual

Ethics review

Approved WMO Application type: Review commission:

First submission 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 CCMO **ID** NL37311.018.11