HbA1c lowering before surgery in poorly controlled diabetes mellitus; a pilot study

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to study the feasibility of lowering HbA1c before elective surgery in patients with suboptimalpoorly controlled DM (HbA1c >7%/53 mmol/mol).

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

Summary

ID

NL-OMON44634

Source
ToetsingOnline

Brief title
The HALT study

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
Diabetes mellitus; Diabetes

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Anaesthesia, Diabetes mellitus, HbA1c, Surgery

Outcome measures

Primary outcome

the main outcome parameter is the proportion of patients in which HbA1c lowering is successful (ie > 10 mmol/mol decrease inclusion-surgery or HbA1c before surgery <53 mmol/mol), comparing HbA1c at inclusion with HbA1c on the day of surgery.

Secondary outcome

As secondary outcome we will ask the patient to perform a fasting plasma glucose fingerstick measurement in the week of study inclusion and on the day of surgery. Also, complications will be registered for evaluation, although this study will to assess any relation between HbA1c and complications.

Study description

Background summary

Preoperative HbA1c values are related to the risk of postoperative complications and mortality in patients with diabetes mellitus (DM). Therefore, the effect of preoperative HbA1c lowering on postoperative complications in poorly regulated diabetes mellitus (DM) patients should be studiedevaluated. However, until now it is unknown whether it is possible at all to lower HbA1c in patients awaiting elective surgery within a relatively short time period.

Study objective

to study the feasibility of lowering HbA1c before elective surgery in patients with suboptimalpoorly controlled DM (HbA1c >7%/53 mmol/mol).

Study design

We will perform a single-centre open label pilot trial.

Intervention

All participating subjects will be referred to the in-hospital diabetes nurse (IHDN) for optimisation of their DM treatment.

Study burden and risks

Risk associated with this study are is comparable to routinely lowering HbA1c in the outpatient setting. The main risk is therefore hypoglycaemia, and this will be prevented as much as possible in clinical practice . Possible benefit is improvement of diabetes regulation and reduction in postoperative complications. In general, this study will be the first step towards a randomized controlled trial, studying the possible benefits of lowering postoperative complications in patients with DM.

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

- Diagnosis of DM type 2 at least 3 months prior to the screening
- Adult patients, age 18-80 years inclusive
- HbA1c >7% (53 mmol/mol) as measured at the pre-assessment clinic
- Scheduled for elective surgery
- Willing and able to provide written informed consent

Exclusion criteria

- Emergency surgery or scheduled surgery < 3 weeks
- Palliative oncological surgery
- Underlying condition that does not allow patients to participate in the study

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-10-2017
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	06-07-2017
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

ID: 29027
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL61715.018.17
Other	volgt
OMON	NL-OMON29027