HbA1c verlaging voorafgaand aan een operatie

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29027

Source
Nationaal Trial Register

Brief title
The HALT study

Health condition

Diabetes mellitus
Surgery
Anaesthesia
HbA1c

Sponsors and support

Primary sponsor: Academic Medical Centre, Amsterdam
Source(s) of monetary or material Support: self-financing research

Intervention

Outcome measures

Primary outcome

The main outcome parameter is whether it is possible to lower HbA1c > 1mmol/mol in the participating subjects or not.

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

Rationale: 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 evaluated. However, until now it is unknown whether it is possible at all to lower HbA1c in patients awaiting elective surgery.

Objective: To study the feasibility of lowering HbA1c before elective surgery in patients with suboptimally controlled DM (HbA1c >53 mmol/mol).

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

Study population: Fifteen adult patients (18-80) with poorly regulated DM type 2, scheduled for elective surgery.

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

Main study parameters/endpoints: 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 (during pre-assessment) with HbA1c on the day of surgery.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Risk associated with this study is comparable to routinely optimizing diabetes care and thereby lowering HbA1c in the outpatient setting. The main risk is 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.

Study objective

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 evaluated. However, until now it is unknown whether it is possible at all to lower HbA1c in patients awaiting elective surgery within a short time period.

Therefore the objective of this project is to study the feasibility of lowering HbA1c before elective surgery in patients with poorly controlled DM (HbA1c >7%/53 mmol/mol).

Study design

Screening

Patients with DM presenting at the outpatient anaesthesiology pre-assessment clinic will be asked to participate in the study. As standard clinical procedure, blood will be drawn for HbA1c determination for all patients with DM scheduled for surgery. Based on the outcome, patients that have an HbA1c >7% (53 mmol/mol) and are willing to participate will be contacted by the IHDN.

Intervention

The IHDN will evaluate the current DM treatment in a first phone contact. The IHDN will provide a treatment advice to optimise the current treatment, if necessary in cooperation with the patient’s primary care physician or other care providers treating the patient for DM. Follow-up and outpatient visits will be planned if deemed necessary by the IHDN. Optimisation of therapy is patient dependent, but will be performed according to the NHG standard and AMC diabetes protocols.

Day of surgery

Blood will be drawn for HbA1c determination on the day of surgery. A fasting fingerstick glucose measurement is performed.

Intervention

Patients willing to participate and meeting the in- and exclusion criteria will be referred to the in-hospital diabetes nurse (IHDN). The IHDN will contact the patient by phone and evaluate the current DM treatment. The IHDN will provide a treatment advice to optimise the current treatment, if necessary in cooperation with the patient’s primary care physician. Follow-up and outpatient visits will be planned if deemed necessary by the IHDN. Optimisation of therapy is patient depending, but will be performed according to the NHG standard and AMC diabetes protocols. The IHDN is supervised by prof. dr. J.H. DeVries, endocrinologist involved in this study. On the day of surgery, blood will be drawn for a final HbA1c determination.

Contacts

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Eligibility criteria

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
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2017
Enrollment:	20
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 44634
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL6143
NTR-old	NTR6298

Register	ID
CCMO	NL61715.018.17
OMON	NL-OMON44634

Study results