Individualised Preoperative Optimisation of Glycaemic Control in Patients with Diabetes Mellitus

Published: 09-10-2019
Last updated: 12-04-2024

The primary objective of this study is to answer whether improving preoperative glycaemic control in patients with poorly controlled diabetes mellitus can lower fasting glucose levels on the day of surgery.Secondary objectives are to determine...

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

Summary

ID

NL-OMON48583

Source
ToetsingOnline

Brief title
The IPOD trial

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
diabetes, diabetes mellitus

Research involving
Human

Sponsors and support

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

Intervention

Keyword: diabetes mellitus, glucose, glycaemic control, preoperative

Outcome measures

Primary outcome

The primary endpoint of the study will be the preoperative fasting glucose concentration.

Secondary outcome

Secondary outcomes are postoperative blood glucose concentrations, incidence of hyperglycaemia and hypoglycaemia (glucose >10 mmol l-1 or <4 mmol l-1, respectively) and change from baseline HbA1c, fructosamine, and 1,5-anhydroglucitol. Finally, number of days at home up to 30 days after surgery will be assessed, which is a single, pragmatic, patient-centred outcome.

Study description

Background summary

Poor glycaemic control, indicated by an elevated HbA1c, is correlated to poor postoperative outcome in patients with diabetes mellitus undergoing surgery. However, improving glycaemic control before surgery has not been extensively studied so far. Reducing perioperative blood glucose has been associated with a decrease in postoperative complications. We hypothesise that improving glycaemic control using an individualised approach guided by a specialised diabetes care nurse, will significantly lower preoperative fasting glucose, which is associated with improved perioperative glucose control and less postoperative complications.

Study objective

The primary objective of this study is to answer whether improving preoperative glycaemic control in patients with poorly controlled diabetes mellitus can

lower fasting glucose levels on the day of surgery.
Secondary objectives are to determine whether preoperative consultation with a specialised diabetes care nurse is effective in improving average glycaemic control as well as postoperative outcomes.

Study design

Pragmatic, non-blinded, randomised, clinical intervention study.

Intervention

On the day of preoperative consultation, HbA1c will be measured. Patients with an HbA1c <53 mmol/mol will proceed to surgery according to standard care. Patients with an HbA1c >=53 mmol/mol and < 100 mmol/mol will be randomised to an intervention group or control group. Patients in the intervention group will be contacted by a diabetes care nurse for optimisation of their glycaemic control before surgery. Patients in the control group will proceed to surgery according to standard care.

Study burden and risks

For study purposes 12 ml of blood will be drawn at two timepoints. At the outpatient clinic, an extra bloodsample will be drawn during the preoperative venipuncture which is part of standard care. On the day of the operation, blood will be drawn using the i.v. the patient already received before the operation. Therefore, no extra venipunctures will be performed for study purposes. Patients in the intervention group will be contacted by the diabetes care nurse for optimisation of their glycaemic control. All patients will be contacted at 30 days after surgery.

Risks associated with the present study are deemed minimal since no investigational products will be used and treatment adjustments are done by a nurse specialised in guiding patients with diabetes mellitus and who is supervised by a consultant endocrinologist. Possible benefits for patients are a possible reduction in postoperative complications as well as a long term improvement in glycaemic control, also after surgery.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105AZ

NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Diabetes mellitus type 2 (diagnosis at least 3 months prior to pre-operative screening)
- Age 18 - 85 years
- Elective non-cardiac surgery
- Scheduled for surgery at least 7 days from date of screening
- Informed consent

Exclusion criteria

- Bariatric surgery
- Palliative surgery
- Outpatient or day case surgery
- (Potentially) pregnant or breast-feeding
- Unable to communicate in Dutch or English, psychiatric disorder, known therapy incompliance or deemed unfit by the researchers for another reason

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-02-2020
Enrollment:	256
Type:	Actual

Ethics review

Approved WMO Date:	09-10-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-06-2020
Application type:	Amendment
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	NL67034.018.18