Optimising control of diabetes before surgery

No registrations found.

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

Summary

ID

NL-OMON23762

Source
NTR

Brief title
The IPOD trial

Health condition

diabetes mellitus
preoperative
glucose
glycaemic control
suikerziekte
preoperatief

Sponsors and support

Primary sponsor: Academic Medical Center
Source(s) of monetary or material Support: Academic Medical Center

Intervention

Outcome measures

Primary outcome

The primary endpoint of the study will be the number of days at home up to 30 days after surgery (DAH30), which is a single,
pragmatic, patient-centred outcome.

Secondary outcome

Secondary outcomes are preoperative and postoperative blood glucose concentrations, incidence of hyperglycaemia and
hypoglycaemia (glucose >10 mmol/l or <4 mmol/l, respectively) and change from baseline HbA1c, fructosamine, and 1,5-
anhydroglucitol.

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. We hypothesise that improving glycaemic control, using an individualised approach
guided by a specialised diabetes care nurse, will improve postoperative outcomes, measured as number of days
spent at home in the thirty days after surgery.
In general, this study will provide more insight in the importance of glycaemic control before surgery and its ability
to improve postoperative outcomes.

Study objective

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. We hypothesise that improving glycaemic control, using an individualised approach guided by a specialised diabetes care nurse, will improve postoperative outcomes, measured as number of days spent at home in the thirty days after surgery.

Study design

- Preoperative consultation: blood glucose, HbA1c, fructosamine, 1,5 AG

- Day of surgery: blood glucose, HbA1c, fructosamine, 1,5 AG.

- 30 days after surgery: number of days at home up to 30 days after surgery

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 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.

Contacts

Public
Academisch Medisch Centrum
Postbus 22660

A.H. Hulst
Amsterdam 1100 DD
The Netherlands
0615222469
Scientific
Academisch Medisch Centrum
Postbus 22660

A.H. Hulst
Amsterdam 1100 DD
The Netherlands
0615222469

Eligibility criteria

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)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2018
Enrollment:	200
Type:	Anticipated

Ethics review

Not applicable
Application type: Not applicable

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
NTR-new	NL7288
NTR-old	NTR7497
Other	67034 : ABR

Study results