Optimising control of diabetes before surgery

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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....

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23762

Bron
NTR

Verkorte titel
The IPOD trial

Aandoening

diabetes mellitus
preoperative
glucose
glycaemic control
suikerziekte
preoperatief

Ondersteuning

Primaire sponsor: Academic Medical Center
Overige ondersteuning: Academic Medical Center

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

- 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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-10-2018
Aantal proefpersonen:	200

Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7288
NTR-old	NTR7497
Ander register	67034 : ABR

Resultaten