Study of alternative drug to insulin for the treatment of high blood glucose concentration in cardiac surgery patients

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We hypothesize that liraglutide treatment, initiated before cardiac surgery, is effective in lowering the number of patients needing perioperative insulin adjustments and reducing the total amount of insulin needed in the perioperative period when...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON29585

Bron
Nationaal Trial Register

Verkorte titel
GLOBE trial

Aandoening

Diabetes Mellitus
Hyperglycaemia
Cardiac Surgery

Ondersteuning

Primaire sponsor: Academic Medical Center Amsterdam
Overige ondersteuning: Novo Nordisk A/S Denmark

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The main outcome measure is the proportion of patients needing insulin therapy in the perioperative period (morning of surgery until transfer to the Intensive Care Unit)

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: In the vast majority of patients undergoing cardiac surgery, hyperglycaemia develops during and after surgery. There is a clear association between hyperglycaemia and postoperative complications. The implementation of perioperative insulin treatment is however hampered by risk of hypoglycaemia. Glucagon Like Peptide 1 (GLP-1) therapy is a promising treatment for perioperative hyperglycaemia during cardiac surgery. It has the potential of lowering glucose and reducing the need for insulin therapy, thereby lowering the risk of iatrogenic hypoglycaemia.

Objective: We hypothesize that liraglutide treatment (a GLP-1 analogue), initiated before cardiac surgery, is effective in lowering the number of patients needing perioperative insulin adjustments and reducing the total amount of insulin needed in the perioperative period when aiming for a moderate glucose target of < 8 mmol l-1.

Study design: We will perform a randomized double blind placebo controlled trial in 4 Dutch cardiac surgery centres.

Study population: We will include patients scheduled for elective cardiac surgery, without diabetes mellitus or diabetes mellitus type 2 with a maximal pre-admission total daily insulin treatment dose of ≤0.5 IU kg-1.

Intervention: Patients will be randomized (1:1) to perioperative liraglutide treatment or placebo. Liraglutide or placebo 0.6 mg subcutaneously (sc) the day before surgery and 1.2 mg sc on the day of surgery will be administered. In both arms the glucose target range is <8 mmol l-1.

Main study parameters/endpoints: The main study endpoint is reduction in the number of patients needing perioperative insulin treatment when aiming for plasma glucose < 8 mmol l-1.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: For study purposes, an additional 18.4 ml of blood will be drawn. This will be taken from intravenous or intra-arterial catheters that have been inserted for clinical purposes. Common adverse events with liraglutide treatment are related to the

gastrointestinal system, nausea and diarrhoea as reported most frequently. In addition, there is a small risk of hypoglycaemia, which is minimized by frequent glucose monitoring. All adverse events are mostly mild and the drop-out rate from clinical trials due to adverse events has been low. Patient might benefit from this intervention by improved perioperative glucose control without insulin. This reduces hypoglycaemia risk and might reduce other postoperative complications. In general this study will provide more insight in the effect of liraglutide as a glucose-lowering agent to prevent insulin use in the perioperative setting.

Doel van het onderzoek

We hypothesize that liraglutide treatment, initiated before cardiac surgery, is effective in lowering the number of patients needing perioperative insulin adjustments and reducing the total amount of insulin needed in the perioperative period when aiming for a moderate glucose target of < 8 mmol l-1

Onderzoeksopzet

Inclusion and informed consent: preoperative clinic.

Randomization: day before surgery

Evening before surgery: liraglutide/placebo 0.6 mg

Day of surgery: liraglutide/placebo 1.2 mg + routine and study laboratory measurements.

Transfer to ICU: stop intervention

30 days after surgery: end follow-up.

Onderzoeksproduct en/of interventie

Patients will be randomized (1:1) to perioperative liraglutide treatment or placebo. Liraglutide or placebo 0.6 mg subcutaneously (sc) the day before surgery and 1.2 mg sc on the day of surgery will be administered.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• Adult patients, aged 18-80 years (inclusive),

• No known diabetes mellitus, or

• Known diabetes mellitus type 2 on oral glucose lowering medication, diet or total daily insulin dose ≤0.5 IU/kg

• Scheduled for an elective cardiac surgical procedure.

• Informed consent obtained before any trial-related activities are carried out.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• Diabetes mellitus type 1

• Emergency surgery

• Receiving oral corticosteroid therapy

• History of pancreatic surgery or acute or chronic pancreatitis

• Personal or family history of medullary thyroid cancer (MTC) or Multiple Endocrine Neoplasia23 syndrome type 2 (MEN2)

• Heart failure NYHA class III or IV

• Serum-creatinine ≥ 133 µmol l-1 for males and ≥ 115 µmol l-1 for females

• Female of child-bearing potential who is pregnant, breast-feeding or intend to become pregnant or is not using adequate contraceptive methods

• Current treatment with GLP-1 analogues

• Known or suspected allergy to trial products or other drugs in the same class

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	09-06-2017
Aantal proefpersonen:	274
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	04-01-2017

Soort: Eerste indiening

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	NL6176
NTR-old	NTR6323
Ander register	EudraCT + WHO UTN : 2017-000043-40 + U1111-1183-2689

Resultaten