Continuation of Metformin during surgery in patients with diabetes mellitus type 2

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Continuation of metformin will lower the postoperative blood glucose levels in patients with diabetes mellitus type 2

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24837

Bron
NTR

Verkorte titel
MD Trial

Aandoening

Diabetes Mellitus
Suikerziekte

Ondersteuning

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Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The difference in postoperative glucose values 2 hours after surgery

Toelichting onderzoek

Achtergrond van het onderzoek

SUMMARY

Rationale:

Metformin, a widely used oral glucose lowering agent for patients with diabetes mellitus type 2, has been associated with lactate acidosis, especially in patients with co-morbidity - such as kidney- and heart failure. For this reason metformin is usually stopped before surgery1. This is also recommended by several guidelines2,3 for care of diabetic patients during the perioperative period. However, recent (meta-)analyses demonstrated that this fear for lactate acidosis is not supported by the available evidence4. In contrast, the discontinuation of metformin before surgery predisposes patients to perioperative hyperglycaemia, leading to postoperative complications. Therefore, following the guidelines might – in this case – lead to worse outcome of respective patients. In this randomized controlled trial we will investigate the glucose lowering potential as well as the safety regarding lactate acidosis of continuing metformin during non-cardiac surgery, as compared to discontinuation of metformin 24 hours before surgery.
A glucose lowering effect of 1 mmol/l after continuation of metformin would be clinically significant5,6 and relevant, because of the possible decrease of postoperative complications and length of hospital stay with stricter blood glucose control.

Objective:

The objective of the study is to investigate the glucose lowering potential and safety of continuation of Metformin during non-cardiac surgery, compared to discontinuation of metformin 24 hours before surgery.

Study design:

Randomised Controlled Trial

Study population:

Patients with diabetes Mellitus type 2 undergoing non-cardiac surgery

Main study parameter/endpoints:

Primary endpoint:

 The difference in postoperative glucose values 2 hours after surgery and

Secondary endpoints:

 The difference in fasting glucose values at day 1 after surgery.

• The difference in lactate levels 2 hours after surgery and at day 1 after surgery.

• The difference in the amount of insulin administered during surgery.

• The occurrence of mild and severe hypoglycaemia (glucose <4.0 mmol/l and <2.3 mmol/l, respectively)

• The difference in length of stay (days) and postoperative complications 30 days after surgery.

Intervention:

During the pre-assessment visit, patients will be given written information about the study. The participants will be randomized to one of the two treatment arms: continuation of metformin (CM) arm or discontinuation (stop) of metformin (SM). Subjects randomised to the CM arm will receive their normal dose of metformin on the day of surgery. For subjects in the SM arm, metformin is discontinued on the day of surgery and restarted when the patient resumes oral intake. If necessary, glucose will be adjusted with boluses of insulin according to the in-house algorithm in both study groups. In both study arms, glucose will be measured every 60 minutes starting 30 minutes prior to surgery until the end of discharge from the recovery. Blood will be drawn 30 min prior to surgery, 2 hours after surgery and on day 1 postoperatively to measure values of lactate.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:
Prior to surgery, HbA1C, lactate and fasting glucose will be obtained. Two hours after surgery and on day 1 postoperatively, blood glucose and lactate will be measured in whole venous blood with blood gas analyses (Radiometer Copenhagen). Common adverse events with metformin treatment are related to the gastrointestinal system, with nausea and diarrhoea reported most frequently. However these adverse events usually occur when metformin treatment is initiated. As patients are already on metformin treatment we don’t expect these events to occur. Metformin has a low risk of developing hypoglycaemia. There will be extensive glucose monitoring to detect any hypoglycaemia perioperatively, and adequate therapy can then be initiated. A possible benefit is a better glycaemic control during surgery,

probably leading to a reduction of postoperative complications.
A patient has the right to withdraw from the study at any time. Reasons for dropouts, if available, will be documented.

Doel van het onderzoek

Continuation of metformin will lower the postoperative blood glucose levels in patients with diabetes mellitus type 2

Onderzoeksopzet

every hour from 30 minutes before surgery untill 2 hours after surgery and the first day postoperative

Onderzoeksproduct en/of interventie

Stop metformin use 24 hours preoperatively in patients with diabetes mellitus type 2 that are allready on metformin for more than 3 months

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Signed informed consent

Aged 18-80 years

Scheduled for elective non-cardiac surgery

Known diabetes mellitus type 2 for > 3 months

Using metformin > 3 months

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Insulin use

Planned day case/outpatient surgery

Planned OR-duration ≤ 45 min

Planned ICU stay post-operatively

Existing severe liver disease or alcohol abuse

Known renal function impairment

Planned corticosteroid treatment perioperatively

Females of child bearing potential who are pregnant, breast-feeding or intend to become pregnant or are not using adequate contraceptive methods (adequate contraceptive measures as required by local law or practice)

Any condition that the local investigator feels would interfere with trial participation or the evaluation of results

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-07-2015
Aantal proefpersonen:	70
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	17-06-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 41974
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5122
NTR-old	NTR5254
CCMO	NL51964.018.15
OMON	NL-OMON41974

Resultaten