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

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24837

Source
NTR

Brief title
MD Trial

Health condition

Diabetes Mellitus
Suikerziekte

Sponsors and support

Primary sponsor: Prof. Dr. W.S. Schlack
Department of Anesthesiology, Academic Medical Center AMC, Meibergdreef 9, 1100 DD Amsterdam
Source(s) of monetary or material Support: Prof. Dr. W.S. Schlack
Department of Anesthesiology, Academic Medical Center AMC, Meibergdreef 9, 1100 DD Amsterdam

Intervention

Outcome measures

Primary outcome

The difference in postoperative glucose values 2 hours after surgery

Secondary outcome

The difference in fasting glucose values at day 1 postoperatively.

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

The difference in the amount of insulin administered during surgery.

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

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

Study description

Background summary

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.

Study objective

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

Study design

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

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2015
Enrollment:	70
Type:	Anticipated

Ethics review

Positive opinion

Date:	17-06-2015
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 41974
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

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

Study results