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

Published: 12-06-2015
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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.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Interventional

Summary

ID

NL-OMON41974

Source
ToetsingOnline

Brief title
MD trial

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
Diabetes

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Diabetes Mellitus, Metformin, Perioperative

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 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.

Study description

Background summary

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 surgery. This is also recommended by several guidelines 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 evidence. 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 significant and relevant, because of the possible decrease of postoperative complications and length of hospital stay with stricter blood glucose control.

Study 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

National Multicenter Randomised Controlled Trial

Intervention

Stopping metformin use 24 hours preoperatively.

Study burden and risks

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.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

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:	Other
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-07-2015
Enrollment:	70
Type:	Actual

Ethics review

Approved WMO

Date:	12-06-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 24837
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL51964.018.15
OMON	NL-OMON24837