Improving metabolic control during and after pancreatic surgery using continuous glucose monitoring (TIMECOG trial): a pilot randomised controlled trial

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We hypothesise that using a continuous subcutaneous glucose monitor during pancreatic surgery, will significantly improve percentage of time spent in glycaemic target range (i.e. glucose ≥ 4 mmol/l and < 10 mmol/l).

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29664

Source
NTR

Brief title
TIMECOG trial

Health condition

Pancreatic disease, diabetes mellitus

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: Sponsor and Dexcom, Inc.

Intervention

Outcome measures

Primary outcome

Percentage of time spent in glycaemic target range (i.e. glucose ≥ 4 mmol/l and < 10 mmol/l).

Secondary outcome

Secondary outcomes include QoR-40,9 postoperative complications after 30 days and incidence of DM de novo.

Study description

Background summary

Pancreatic surgery often results in impaired glucose metabolism or diabetes mellitus, depending on the endocrine function of the residual pancreatic parenchyma. Poor perioperative glycaemic control has been associated with unfavourable outcome after surgery. Therefore, patients undergoing pancreatic surgery may substantially benefit from improved glucose monitoring. In this study we will assess the efficacy of continuous glucose monitoring for perioperative glucose control in patients undergoing pancreatic surgery.

Study objective

We hypothesise that using a continuous subcutaneous glucose monitor during pancreatic surgery, will significantly improve percentage of time spent in glycaemic target range (i.e. glucose ≥ 4 mmol/l and < 10 mmol/l).

Study design

Glucose will be measured by both the sensor and according to standard of care (POCT analyser) during the intraoperative and early postoperative period (day +1). On day + 30, follow-up by telephone or email is scheduled, after which trial participation ends.

Intervention

Patients will receive a subcutaneous glucose sensor on the day before surgery. The glucose values measured will be used to guide treatment during the intraoperative and early postoperative period. Glucose measurements will be confirmed using a point-of-care analyser.

Contacts

Public
Amsterdam UMC locatie AMC
Robert van Wilpe

020 - 566 25 33
Scientific
Amsterdam UMC locatie AMC
Robert van Wilpe

020 - 566 25 33

Eligibility criteria

Inclusion criteria

Adult patients, aged between 18 and 85, undergoing either pancreaticoduodenectomy or distal pancreatectomy, willing and able to provide written informed consent.

Exclusion criteria

Unable to communicate in Dutch or English, psychiatric disorder or any other condition the local investigator feels would interfere with trial participation or measurements

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2020
Enrollment:	72
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
NTR-new	NL8055
CCMO	NL70513.018.19

Study results