Increasing habitual physical activity to reduce the surgical risk of hyperglycemia and complications in patients with the metabolic syndrome

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In the POSitive project we aim to investigate whether the diagnosis of the metabolic syndrome could be embedded in the clinical practice of the POS. The use of the POS clinic as screening platform for health prevention contributes to early case…

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

Summary

ID

NL-OMON39014

Source
ToetsingOnline

Brief title
POSitive II study

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
Metabolic syndrome, prediabetes

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

Source(s) of monetary or material Support: ZonMw Preventie subsidie

Intervention

Keyword: Daily activity, Intraoperative hyperglycemia, Metabolic syndrome, Prediabetes

Outcome measures

Primary outcome

The effect of the POSitive program will be measured as the incidence of perioperative hyperglycemia in the intervention group when compared to controls.

Secondary outcome

Intervention endpoints:

- Change in daily steps taken

Health condition endpoints:

- Change in body mass index
- Change in waist circumference
- Change in blood pressure
- Change in fasting blood glucose
- Change in fasting blood lipid levels
- Change in aerobic fitness measured by the VO2 max
- Change in fat free mass and percentage total body fat

Condition endpoint:

- Number of patients with a normal fasting blood glucose (< 6.1 mmol/l) but with impaired glucose tolerance measured using an oral glucose tolerance test

(OGTT; blood glucose > 7.8 mmol/l at 2-hours after ingestion of a glucose load).

Surgery-related endpoints:

- Perioperative use of insulin

- Number of perioperative and postoperative complications (infections, use of antibiotics, renal impairment, cardiac arrhythmia and myocardial ischemia)

- Length of hospital stay

Postoperative endpoints:

- Health condition and use of health care facilities after 2 weeks following surgery.

- Assessment of physical activity level by a questionnaire at 6 months following surgery.

Population endpoints that may influence the effect of the POSitive program:

- Use of statins or antidiabetic drugs

- Age

- Ethnical background

- Socioeconomic status

Study description

Background summary

About 15% of the general adult patient population visiting the Preoperative Screening (POS) outpatient clinic for a routine preoperative health risk

assessment by an anesthesiologist is diagnosed with central obesity. Although about 35% of these patients silently suffer from the metabolic syndrome, most patients leave the POS clinic without an appropriate diagnosis of their cardiometabolic state.
In addition to the latent risk of an undiagnosed metabolic syndrome for the development of cardiovascular disease and diabetes, cardiometabolic derangements may become abundant during stressful events like anesthesia and surgery, leading to perioperative hyperglycemia. Perioperative hyperglycemia is a well-known predictor for postoperative complications like infections and a prolonged hospital stay. Despite the tangible, but undiagnosed presence of the metabolic syndrome in the surgical population, the POS clinic is not considered as screening platform for cardiometabolic disease and the implementation of preventive interventions.

Study objective

In the POSitive project we aim to investigate whether the diagnosis of the metabolic syndrome could be embedded in the clinical practice of the POS. The use of the POS clinic as screening platform for health prevention contributes to early case finding of the metabolic syndrome in surgical patients. We further aim to implement the POSitive habitual physical activity program in patients who are diagnosed with the metabolic syndrome in the weeks preceding surgery in order to improve the health condition of these patients, and reduce the risk for perioperative hyperglycemia. We hypothesize that the POS setting is an effective platform for new onset diagnosis of the metabolic syndrome and the institution of a habitual activity lifestyle program.

Study design

Screening of about 1700 patients at the POS for central obesity and a HbA1c > 5.5% with or without mild-severe hypertension (niet-WMO part).
In the presence of the metabolic syndrome, patients will be randomized into a control arm (passive lifestyle advice, visit general practitioner) or the POSitive intervention arm (active lifestyle advice based on the individual needs, coaching, visit general practitioner). Patients will follow the intervention until the day of surgery (WMO part).

Intervention

Control group

Patients in the control group are not subjected to the daily habitual physical activity intervention and do not receive telephone coaching. Daily activity is measured by an accelerometer with a one-week memory function, which is blinded for the participant.

POSitive program group

The POSitive program promotes an increase in habitual physical activity in patients diagnosed with new onset metabolic syndrome. Patients receive a pedometer. This program consists of the following components:

- Increasing awareness of an unhealthy lifestyle (risk communication)
- Offering of practical lifestyle improvement solutions to show the changeability of the physical health state
- Tailor-made action plans to increase daily habitual physical activity

Study burden and risks

The present study is primarily developed to show that many patients silently suffer from cardiometabolic disease. Using the POS as screening platform we may not only detect de novo prediabetes/diabetes, but may additionally off passive lifestyle advice (control group) or active lifestyle coaching (POSitive group) to prevent further development of cardiometabolic disease and the development of intraoperative hyperglycemia. The burden and risks that are associated with the study is, to our opinion, acceptable in light of the possible health benefits for the patients on the long run.

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

Abdominal weight circumference of >= 102 cm in males and >= 88 cm in females
Patients who are able to increase their habitual physical activity levels.
A HbA1c > 5.5%
Age 18-80 years
Elective non-cardiac surgery with a waiting time of > 5 weeks

Exclusion criteria

Existing diabetes mellitus type 1/2
Diagnosis of type 2 diabetes mellitus during the POSitive program screening (blood glucose > 11 mmol/l at 2 hours following a glucose load). New onset diagnosis of type 2 diabetes mellitus needs confirmation by a general practitioner.
Myocardial ischemic disease
Patients with disabilities that prohibit an increase in habitual physical activity due to muscular or orthopedic disorders.

Study design

Design

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

Primary purpose: Diagnostic

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	27-05-2013
Enrollment:	582
Type:	Actual

Ethics review

Approved WMO Date:	27-02-2013
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

No registrations found.

In other registers

Register	ID
CCMO	NL42863.029.12