The effect of a preoperative lifestyle intervention in patients with acquired risk factors on perioperative glucose control and hemodynamics

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The primary objective of this study is to investigate whether skeletal muscle glucose metabolism, perioperative glucose control and hemodynamics are affected by increasing physical activity in the weeks preceding surgery in patients identified with...

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

Summary

ID

NL-OMON36362

Source
ToetsingOnline

Brief title
POSitive study

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Therapeutic procedures and supportive care NEC

Synonym
Impaired glucose tolerace, metabolic syndrome

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Glucose regulation, Hemodynamics, Lifestyle intervention, Perioperative

Outcome measures

Primary outcome

Changes in muscular GLUT-4 expression after increased physical activity

Secondary outcome

*Changes in physical activity during lifestyle intervention (daily steps taken)

*Influence of increased physical activity on perioperative glucose control

(measured as longitudinal plasma glucose levels during surgery)

*Influence of increased physical activity on perioperative hemodynamics.

Influence of increased physical activity on heart rate variability

Study description

Background summary

Health risk assessment by an anesthesiologist in the weeks preceding surgery is elaborated to identify patients at risk for perioperative complications. This assessment further enables individualized perioperative management that aims at optimizing the health condition of the patient. The majority of patients suffer from acquired health risk factors, which may additionally contribute to impaired skeletal muscle glucose and fatty acid metabolism, GLUT-4 protein expression, disturbed perioperative glucose control and hemodynamics. It has been shown that augmentation of physical activity may be beneficial for muscular GLUT-4 expression, but it is unknown whether this may additionally result in improved perioperative control of glucose and hemodynamics. Here we aim to investigate whether structural exercise in the six weeks preceding surgery may contribute to improvement of the metabolic and hemodynamic profile

of surgical patients.

Study objective

The primary objective of this study is to investigate whether skeletal muscle glucose metabolism, perioperative glucose control and hemodynamics are affected by increasing physical activity in the weeks preceding surgery in patients identified with two or more acquired health risk factors and impaired glucose tolerance (IGT).

Study design

Prospective, single center intervention study

Intervention

Patients are stimulated to increase their daily physical activity by increasing daily steps taken for a minimum of 6 consecutive weeks

Study burden and risks

Site visits: A total of three additional site visits, one additional questionnaire and three additional blood samples by vena puncture on top of regular practice will be required to collect all data.
Metabolism: Determination of fasting plasma glucose (FPG) and oral glucose tolerance test (OGTT) after overnight fasting requires extra blood sampling.
Physical condition: Patients perform a 6 minute walk distance test (6MWD) during the preoperative assessment and the day before surgery.
GLUT-4 expression: Two muscle biopsies will be taken, the first in the preoperative assessment phase under local anesthesia, the second after anesthesia induction. The muscle biopsies may cause a muscle hematoma. An experience investigator will be asked to perform the muscle biopsy to reduce the risk for muscle hemotoma.
Physical activity: patients will increase their physical activity for 6 weeks, which is recorded by a pedometer and in a diary.
Although the burden for the patient is substantial and there are mild risks associated with participation in this study, we believe these outweigh the benefits for the individual patient and the patient population as a whole.

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

The patient has at least two of the following lifestyle risk factors:
- Overweight (BMI >25 kg/m2)
- Hypertension (systolic blood pressure>140 mmHg and/or diastolic blood pressure>90 mmHg)
- Physical inactivity (< 30 min/day of moderate activity, like walking or cycling)
In combination with: Newly identified impaired glucose tolerance;General inclusion criteria
* Newly identified impaired glucose tolerance (IGT)
* Age between 40 and 75 years
* Undergoing elective surgery not sooner than 8 weeks after the PAOC visit
* Non-cardivascular surgery with a minimal duration of 60 minutes
* ASA class I-III
* Able to walk independent of assistance
* Signed informed consent

Exclusion criteria

- Prior diagnosis of diabetes mellitus

- Not fit enough to participate in this study
- ASA class IV

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-09-2011
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO Date:	05-04-2011
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-05-2012
Application type:	Amendment
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	NL35180.029.10