The contribution of a carbohydrate-rich drink preoperatively on postoperative insulin sensitivity and gastric emptying

Published: 20-05-2008
Last updated: 10-05-2024

The primary objective is to investigate whether insulin sensitivity can be preserved postoperatively, by giving a simple carbohydrate-rich drink before surgery. Furthermore, to investigate whether gastric passage will be enhanced postoperatively...

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

Summary

ID

NL-OMON31617

Source
ToetsingOnline

Brief title
CArbohydrates PREoperatively and insulin sensitivity (CAPRESE)

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Bone and joint therapeutic procedures

Synonym
gastric passage, insulin sensitivity

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: 4e: WBSO

Intervention

Keyword: carbohydrate-rich drink, gastric emptying, postoperative insulin sensitivity, preoperative

Outcome measures

Primary outcome

The main parameters of the study are insulin resistance.

Secondary outcome

Secondary parameters will be gastric emptying rate hormone levels and well

being.

Study description

Background summary

Fasting before surgery has a large effect on the postoperative condition of the patient. Surgical trauma decreases insulin sensitivity postoperatively. This loss of insulin sensitivity is enhanced when patients are in a fasted state before operation. Furthermore, surgical trauma influences postoperative gastric motility. Patients often feel distressed, experience nausea and vomiting. Fasting before surgery may enhance a delayed restart of normal gastric motility. A preoperative drink may reduce this and instead promote an earlier onset of normal gastric motility.

Study objective

The primary objective is to investigate whether insulin sensitivity can be preserved postoperatively, by giving a simple carbohydrate-rich drink before surgery. Furthermore, to investigate whether gastric passage will be enhanced postoperatively when given a preoperative carbohydrate load. Secondary, gastric hormones will be determined to investigate changes after surgery when given a preoperative carbohydrate-rich drink. Furthermore, the well being of the patient will be investigated all of the groups.

Study design

A double blind, placebo controlled intervention study at the department of orthopedics of the VU medical center, Amsterdam.

Inclusion criteria:
-in need of hipreplacement
-intact mental status
-BMI: 20-25 kg/m2
-stable weight within the previous 3 months
-having obtained his/her informed consent

Exclusion criteria:
-Diabetes Mellitus
-Sliding hiatal hernia
-Paraesophageal hiatal hernia
-Obstruction gastrointestinal tract
-Use of certain medication: thyroid medication, corticosteroids, diuretic medication, antiemetics, antihypertensive medication
-Patients participating in another trial

Intervention

Either one of two carbohydrate-rich drinks or a placebo will be given 3 hours preoperatively. In a subgroup (group B), a gastric emptying scintigraphy will be made before and after surgery. Blood samples will be taken to investigate insulin sensitivity and gastric hormonal changes.

Study burden and risks

The possible benefit of the study is related to the effect of a preoperative carbohydrate load. Oral administration of a carbohydrate-rich drink before surgery can reduce postoperative insulin resistance and may preserve gastric emptying rates. Research showed that both of the drinks can be safely administered to humans and no adverse effects are reported. Part of the patients will undergo a gastric emptying scintigraphy before and after operation. This is an adequate and safe method to measure gastric passage.

Contacts

Public
Vrije Universiteit Medisch Centrum

postbus 7057
1007 MB Amsterdam
Nederland
Scientific
Vrije Universiteit Medisch Centrum

postbus 7057
1007 MB Amsterdam
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Due for elective hip or knee surgery
- Intact mental status
- BMI: 20-25 kg/m2
- Stable weight last three months
- Having obtained his/her informed consent

Exclusion criteria

- Diabetes mellitus patients
- Sliding hiatal hernia
- Paraesophageal hiatal hernia
- Obstruction gastrointestinal tract
- Use of certain medication: thyroid medication, corticosteroids, diuretic medication, antihypertensive medication, antiemetica
- Patients participating in another trial

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2007
Enrollment:	45
Type:	Anticipated

Ethics review

Approved WMO

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	NL19429.029.07