Effect of feeding frequency on glucose and insulin metabolism and substrate partitioning in impaired glucose tolerant (IGT) men

Published: 03-11-2010
Last updated: 03-05-2024

The presently proposed study aims to investigate how different feeding frequencies lead to differences in glucose and insulin metabolism in impaired glucose tolerant (IGT) men.

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

Summary

ID

NL-OMON34114

Source
ToetsingOnline

Brief title
Feeding frequency en glycemic and insulinemic control in IGT men

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
diabetes, obesity

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Nederlandse Zuivelstichting

Intervention

Keyword: 24h glycemic and insulinemic control, Feeding frequency, IGT, substrate partitioning

Outcome measures

Primary outcome

24h glycemic and insulin control

Secondary outcome

substrate partitioning, hunger and satiety questionnaires, FFA, CRP, leptin,

TG, CCK, GLP-1, adiponectin, c-peptide, ghrelin, glucagon, genexpression

profiles from the muscle biopsies

Study description

Background summary

The recent escalating obesity trend in man is due to an imbalance between energy intake and energy expenditure. Energy intake is influenced by the effect of food*s energy density, total energy content and feeding frequency and the extent to which these alter satiety. Of these factors, feeding frequency has received least attention. Epidemiological evidence in human subjects indicates increasing trends in recent years of dietary snacking and increased meal frequency and such studies show positive relationships between snacking and increased energy intake and BMI, illustrating the potential importance of investigating feeding frequency.

Study objective

The presently proposed study aims to investigate how different feeding frequencies lead to differences in glucose and insulin metabolism in impaired glucose tolerant (IGT) men.

Study design

This study is a randomized, controlled crossover study with 1 group of 14 healthy male volunteers. Subjects are exposed to two different diets. To have a same baseline condition before each diet, subjects have to standardize the diet

and activity over the 3 days before the tests. Therefore food-intake and activity diaries have to be filled out before the first test day and repeated exactly similar before other test days (see attachments for food-intake and activity diaries). At arrival, the Continuous Glucose Monitoring System (CGMS) will be inserted in the peri-umbilical region of the subject and subjects enter the respiration chamber at 20.00 h and leave the chamber 36 hours later at 8.00h after a muscle biopsy was taken. The first twelve hours are to accustom to the respiration chamber. Then, energy expenditure measurements are made during 24 hours. During the test satiety questionnaires have to be filled out. Also bloodsamples will be taken at baseline and after a half hour and then hourly.

Intervention

1. high feeding frequency (14 meals a day)
2. low feeding frequency (3 meals a day))

Study burden and risks

Risks as the result of participation in this experiment are minimal.
Venapunctures can occasionally cause a local haematoma or bruise to occur. Some participants report some pain during venapuncture. Insertion of the CGMS could induce some pain, because this system will be placed by means of a needle. The needle will be removed after insertion of this system. however no discomfort is expected from carrying this device. Previous studies have shown that wearing the CGMS does not hinder the subject in his normal functioning.
Due to the local anesthesia, the biopsy is as good as painless. Some participants however, do report a sense of pressing pain during biopsy taking. This tension is very comparable to pain that occurs upon bumping against a table edge. Occasionally the procedure might cause a local haematoma or bruise. To minimize this risk, after taking the muscle biopsy, the wound will be covered with a sterile water-resistant plaster and the leg will be taped with an elastic adhesive compression bandage. The place of incision will leave a small scar. To promote good wound healing, the incision will be sealed with sterile steristrips.
Also participants will be asked if they are claustrophobic, because this could become a problem when they are staying in the respiration chamber and will be excluded if no solution can be found.
No harm from the dietary intervention is to be expected. All diets used during this study are purchases in the local supermarket and used before indicated expiring dates. During the test days meals will be prepared in the kitchen of the department of Human Biology which is solely dedicated for preparing of food for human use.

Contacts

Public
Universiteit Maastricht

Franquinetstraat 36A
6217 KV Maastricht
Nederland
Scientific
Universiteit Maastricht

Franquinetstraat 36A
6217 KV Maastricht
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

impaired glucose tolerant (IGT)
BMI 20-35 kg/m2
non-smoking

Exclusion criteria

diabetes
cardiovascular disease
lactose intolerant
normal glucose levels

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-12-2010
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO

Date:	03-11-2010
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL33407.068.10