Effect of feeding frequency on glucose and insulin metabolism and substrate partitioning

Published: 22-07-2009
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The presently proposed study aims to investigate the effect of feeding frequency on glucose and insulin metabolism and substrate partitioning.

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

Summary

ID

NL-OMON33303

Source
ToetsingOnline

Brief title
Feeding frequency en glycemic and insulinemic control

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,zuivelstichting van de Nederlandse Zuivel Organisatie

Intervention

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

Outcome measures

Primary outcome

24 hr glycemic and insulin control

Secondary outcome

Substrate partitioning, hunger and satiety questionnaries, FFA, CRP, leptin,

TG, CCK, GLP-1, adiponectin, ghrelin, glucagon

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 the effect of feeding frequency on glucose and insulin metabolism and substrate partitioning.

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. Each respiration chamber visit starts after the continuous glucose monitoring system (CGMS) placement plus

preparation time at 21.00h and ends 36 hours later at 9.00h. The first twelve hours are to accustom to the respiration chamber. Then, energy expenditure measurements are made during 24 hours at a temperature of 22°C. During the test satiety questionnaires have to be filled in. 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

Venapunctures can occasionally cause a local heamatoma or bruise to occur.

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

Healthy men
BMI between 18.5 -25 kg/m2
Older than 18 years old and including 35 years old

Exclusion criteria

Diabetes Mellitus
Hypertension
Hypotension
Cardiovasculaire diseases
Asthma and other obstructive pulmonary diseases
Lactose tolerant
Younger than 18 years old and older than 35 years old

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):	21-10-2009
Enrollment:	14
Type:	Actual

Ethics review

Approved WMO Date:	22-07-2009
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	NL28272.068.09