Impact of carbohydrate co-ingestion on the post-prandial anabolic response of protein in young and elderly men

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON35860

Source
ToetsingOnline

Brief title
PRO-CARB study

Condition

- Other condition
- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
nvt

Health condition

spiermetabolisme

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: insulin, muscle, perfusion, protein

Outcome measures

Primary outcome

Muscle protein synthesis rate, expressed as fractional synthetic rate (FSR).

Secondary outcome

Rate of protein digestion and absorption, whole body protein balance and

microvascular perfusion and diameter.

Study description

Background summary

Age related muscle loss (sarcopenia) is assumed to be related to the impaired postprandial muscle protein synthetic response to protein and/or amino acid administration in the elderly vs the young. Co-ingestion of carbohydrate increases post-prandial insulin secretion. Increased insulin secretion affects skeletal muscle blood flow and may therefore affect substrate availability and postprandial muscle protein synthesis. However, it is unclear whether the response to the combined intake of protein and carbohydrates is different in elderly compared to young subjects.
Hypothesis: Adding carbohydrate to a bolus of protein represents an effective strategy to overcome the impaired postprandial muscle protein synthesis in the elderly.

Study objective

The primary objective of the study is to investigate whether carbohydrate co-ingestion augments the in vivo postprandial muscle protein synthetic response after protein ingestion and whether this response is differs between young and elderly subjects. The secondary objective of the study is to assess the effect of carbohydrate co-ingestion on insulin levels and microvascular

perfusion in young and elderly subjects.

Study design

Double-blind, placebo controlled, parallel, human intervention study.

Intervention

The intervention consists of a single test day during which the subjects will receive a drink containing 20 gram intrinsically labelled casein with or without 75 gram carbohydrates. In addition, continuous intravenous tracer infusions of labeled amino acids will be administered. During the test day 18 plasma samples and 4 muscle biopsies are collected over a period of 8* h. Furthermore, muscle skeletal blood flow will be estimated using sidestream darkfield imaging (SDF) in sublingual position.

Study burden and risks

The risks involved in participating in this experiment are minimal. Insertion of the catheters in a vein is comparable to a normal blood draw and the only risk is a small local hematoma. This is the same for the muscle biopsies. Muscle biopsies will be taken through a small (5 mm) incision, following local anesthetics of the skin and muscle fascia, and will heal completely. Muscle biopsies will only be obtained by an experienced physician. The test beverages contain intrinsically labeled dietary protein and carbohydrate which is safe for human consumption and have been used in previous studies (MEC 06-3-064, MEC 07-3-086, MEC 09-3-078.3). The labeled, non-radioactive amino acids tracers that will be infused intravenously are produced according to GMP standards and are completely safe.

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

24 healthy, young male subjects (18-30 y)
24 healthy, elderly male subjects (70-85 y)

Exclusion criteria

• Diabetes
• Obesity (BMI > 30 kg/m2)
• All co-morbidities interacting with mobility and muscle metabolism (e.g. arthrosis, arthritis, spasticity/rigidity, all neurological disorders).
• Hypertension (according to WHO criteria)
• Use of anticoagulants, blood diseases, allergy for lidocain

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-01-2012
Enrollment:	48
Type:	Actual

Ethics review

Approved WMO

Date:	08-08-2011
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	NL36726.068.11