Impact of fat co-ingestion with protein on the post-prandial anabolic response in elderly men

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Protein and amino acid metabolism disorders NEC
Study type	Interventional

Summary

ID

NL-OMON37092

Source
ToetsingOnline

Brief title
PRO-FAT study

Condition

- Protein and amino acid metabolism disorders NEC
- Muscle disorders

Synonym
age-related muscle loss, sarcopenia

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W,TIFN

Intervention

Keyword: Casein, Fat, Muscle protein synthesis

Outcome measures

Primary outcome

The main study endpoint is muscle protein synthesis (MPS) rate. In order to determine the MPS, the following parameters will be measured in blood and muscle tissue:

* Plasma phenylalanine concentration (expressed as *mol/L)

* Plasma enrichment of L-[ring-2H5]-phenylalanine and L-[1-13C]-phenylalanine (expressed as mole percent excess, MPE)

* Muscle protein bound enrichment of L-[ring-2H5]-phenylalanine and L-[1-13C]-phenylalanine (expressed as MPE)

* L-[ring-2H5]phenylalanine and L-[1-13C]-phenylalanine enrichment of the muscle free amino acid pool (expressed as MPE)

Secondary outcome

Secondary endpoints include whole-body protein turnover, and protein digestion and absorption kinetics. The following parameters will be calculated:

* Total rate of phenylalanine appearance and disappearance (= protein turnover)

* Exogenous phenylalanine rate of appearance

* Endogenous phenylalanine rate of appearance (=protein breakdown)

* Plasma availability of phenylalanine

Study description

Background summary

The progressive loss of skeletal muscle mass with aging, or sarcopenia, has a major impact on our healthcare system due to increased morbidity and greater need for hospitalization and/or institutionalization. The age-related loss of skeletal muscle mass is facilitated by a combination of factors, which include a less than optimal diet and a sedentary lifestyle. These factors contribute to a disruption in the regulation of skeletal muscle protein turnover, leading to an imbalance between muscle protein synthesis (MPS) and degradation. One way to overcome this problem is to improve dietary intake of the elderly. It has been well established that nutrient intake greatly affects protein turnover in skeletal muscle tissue. Ingestion of dietary protein stimulates MPS rates and inhibits muscle protein breakdown rates, resulting in an overall positive net protein balance in both the young and elderly. However, it is not clear what the impact is of fat co-ingestion with protein on digestion and absorption kinetics or MPS rates in the healthy elderly men. A study performed by Elliot et al. investigated the effect of whole milk ingestion on net muscle protein balance after resistance exercise using an arteriovenous balance approach. Ingestion of whole milk (containing 50 en% fats) stimulated the post-exercise net uptake of phenylalanine and threonine to a greater extent than ingestion of fat-free milk (containing 6 en% fat). Although, amino acid uptake is indicative of *muscle anabolism*, it is not a direct measure of MPS so no firm conclusions can be deduce from this work. Furthermore, milk also contains a certain amount of carbohydrates (fat-free milk 55 en% and whole milk 30 en%), which does not allow for direct assessment of fat co-ingestion per se. In the present st

Study objective

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Study design

Double-blind randomized intervention study

Intervention

One group (n=12) will consume a test beverage of 350 mL containing 20 g of intrinsically labeled casein, and the other group (n=12) will consume a beverage of the same volume containing 20 g of casein plus 20 g of fat.

Study burden and risks

The burden and risks associated with participation are small. Insertion of the

catheters is comparable to a blood draw and could result in a small hematoma. Muscle biopsies will be taken under local anesthesia by an experienced physician, but may cause some minor discomfort for maximally up to 24 h after completion. The discomfort is comparable to muscle soreness or the pain one has after bumping into a table. We will take 5 and 19 blood samples (8 mL) during the screening and experimental trial respectively. The total amount of blood we draw is less than half the amount of a blood donation and will be completely restored in approximately 1 month. Participants come to the university twice: 1 screening (4 hours) and 1 experimental trial (entire day). For both the screening and the experimental trial, participants have to be fasted, so they are not allowed to eat and drink (except for water) from 22h00 the evening before. Also, 3 days prior to the experimental trial participants should keep their diet as constant as possible, do not perform any type of intense physical exercise, and do not consume alcohol. During the screening we will perform a DEXA and CT scan and an OGTT. Furthermore, we will ask the participants to fill out a medical questionnaire and record their food intake for 2 days prior to the experimental trial. During the experimental trial, we will collect muscle and blood samples, and participants have to consume a test beverage consisting of milk protein with or without milk fat. The intrinsically labeled milk protein and milk fat has been approved for human consumption and has been used in previous METC approved studies. There is no direct benefit for the participants, only their contribution to scientific knowledge and nutritional strategies that prevent muscle loss in the elderly, which will be obtained from this study and used in the future.

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 males
* Age between 55 and 85
* BMI < 30 kg/m2

Exclusion criteria

* Glucose intolerance
* Milk and/or fat intolerance
* Smoking
* Diagnosed GI tract diseases
* Arthritic conditions
* A history of neuromuscular problems
* Any medications known to affect protein metabolism (i.e. corticosteroids, non-steroidal anti-inflammatories, or prescription strength acne medications).
* Use of anticoagulants
* Participation in exercise program
* Hypertention, high blood pressure above 140/90 mmHg

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)

Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-10-2012
Enrollment:	32
Type:	Actual

Ethics review

Approved WMO

Date:	22-08-2012
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
ClinicalTrials.gov	NCT...
CCMO	NL41117.068.12