The impact of habitual dietary protein intake on the 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-OMON38469

Source
ToetsingOnline

Brief title
Pro-Hab 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

Intervention

Keyword: Digestion and absorption kinetics, Habitual protein intake, Muscle protein synthesis, Whey protein

Outcome measures

Primary outcome

The main study endpoint is muscle protein synthesis (MPS) rates. In order to

determine the MPS, the following parameters will be measured:

* Muscle protein-bound L-[D5]-phenylalanine enrichment (expressed as MPE)

* Muscle free (intracellular) L-[D5]-phenylalanine enrichment (expressed as MPE)

* Plasma L-[D5]-phenylalanine enrichment (expressed as MPE)

Secondary outcome

Secondary endpoints include protein digestion and amino acid absorption

kinetics and whole-body protein synthesis, breakdown, oxidation, and net

balance. Therefore, the following parameters will be measured:

* Plasma phenylalanine, tyrosine, and leucine concentration (expressed as *mol/

L)

* Plasma enrichments (in MPE) of:

o L-[1-13C]-phenylalanine

o L-[D5]-phenylalanine

o L-[1-13C]-tyrosine

o L-[D4]-tyrosine

o L-[D2]-tyrosine

o L-[1-13C]-leucine

o L-[1-13C]-alpha-KIC

Other study parameters include plasma glucose and insulin concentrations, age, body weight, body length, BMI, body composition, blood pressure, and leg volume.

Study description

Background summary

During the adult life skeletal muscle mass remains fairly constant until the fourth or fifth decade. Then, the slow process of sarcopenia (the age-related loss of muscle mass) is believed to begin. The maintenance of skeletal muscle mass is regulated by a balance between the opposing processes of muscle protein synthesis and muscle protein breakdown. Food intake, dietary protein in particular, stimulates muscle protein synthesis and allows net muscle protein accretion throughout the day, which allows the normal maintenance of muscle mass in healthy individuals. Many studies have described the postprandial muscle protein synthetic response to protein intake and/or physical activity, and these acute findings have led to recommendations for protein intake for both athletes wishing to gain muscle mass as well as patients and elderly individuals to help them maintaining muscle mass. However, translating the acute findings from a single meal to long-term recommendations is perhaps premature, since scientists know very little with regard to how previous consumed meals affect the anabolic responsiveness to subsequent food intake. A characteristic of the adaptation to habitual high or low protein intake is thought to be associated with a change in the amplitude of diurnal cycle of whole body proteins. If this speculation is accurate, it implies that the muscle protein synthetic responses to feeding (differences between fasting and feeding muscle protein synthesis rates) are adapting to differing habitual protein intake, which may reduce (or enhance) the anabolic responsiveness to protein intake.

Study objective

To gain a more complete scientific understanding, it is necessary to examine whether an adaptation does in fact occur after habitual high or low amounts of protein intake with regard to the anabolic response to subsequent protein intake. In the present investigation, we wish to investigate the impact of the habitual consumption of either high or low protein diets for 14 days on the anabolic responsiveness to a protein meal in healthy elderly.

Study design

single blind intervention study

Intervention

Subjects will receive food bags for 14 days, containing either a low (0.7 g/kg BW/d) or high (1.5 g/kg BW/d) protein diet. Following this (i.e. day 15), the subjects will report to the laboratory in a fasted state and attend a single experimental trial where they ingest 25 g of intrinsically labeled whey protein in 350 mL water.

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 blood samples (1x 10 mL and 4x 5 mL) 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. For both the screening and the experimental trial, subjects have to be fasted, so they are not allowed to eat and drink (except for water) from 22h00 the evening before. Also, 3 prior to the experimental trial subjects should keep their diet as constant as possible, do not perform any type of intense physical exercise, and do not consume alcohol. Furthermore, we will ask the subjects to fill out a dietary record for 3 random days prior to the experimental trial.
The stable isotope amino acids tracers applied in this experiment are not radioactive and are completely safe. The production of the tracers for intravenous administration will occur in a sterile environment according to GMP guidelines.
There is no risk associated with the DEXA scan. The radiation dose emitted during a DEXA scan is 0.001 mSv. This is a very low exposure compared to the total background radiation in the Netherlands, which is ~2.5 mSv/year. For comparison, the radiation dose during a flight higher than 10 km is 0.005 mSV*h-1.
The benefit of participation in this study is that all food will be provided for 14 days.

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 75 y
* BMI between 18.5 and 30 kg/m2

Exclusion criteria

* Lactose intolerance
* Smoking and alcohol abuse
* Diabetes
* 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

* Hypertension, high blood pressure that is above 140/90 mmHg.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-01-2014
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	04-12-2013
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	24-03-2014
Application type:	Amendment
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	NL46530.068.13