Postprandial muscle protein synthesis following wheat protein ingestion in vivo in humans

Published: 04-12-2013
Last updated: 23-04-2024

Primary Objective: To provide evidence for the efficacy of wheat protein and wheat protein hydrolysate when compared with milk proteins as a dietary protein to stimulate postprandial muscle protein synthesis in vivo in healthy older humans....

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

Summary

ID

NL-OMON38800

Source
ToetsingOnline

Brief title
Plant based protein 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: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W,Tereos Syral

Intervention

Keyword: Digestion and absorption kinetics, Muscle protein synthesis, Protein type, Wheat 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-[U-13C]-phenylalanine enrichment (expressed as MPE)

* Muscle free (intracellular) L-[U-13C]-phenylalanine enrichment (expressed as

MPE)

* Plasma L-[U-13C]-phenylalanine enrichment (expressed as MPE)

Secondary outcome

Secondary endpoints include whole-body protein metabolism (synthesis,

breakdown, oxidation, and net balance). Therefore, the following parameters

will be measured:

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

* Plasma enrichments (in MPE) of:

o L-[U-13C]-phenylalanine

o L-[U-13C]-tyrosine

o L-[3,5-2H2]-tyrosine

Other study parameters include plasma leucine, glucose, and insulin

concentrations, age, body weight, body length, BMI, body composition, blood

pressure, and leg volume.

Study description

Background summary

The progressive loss of skeletal muscle mass with aging, or sarcopenia, has a major impact on our health care system due to increased morbidity and greater need for hospitalization and/or institutionalization. One way to prevent skeletal muscle loss is to improve dietary intake of the elderly. Both whey and casein seem to offer an anabolic advantage over soy protein for promoting muscle hypertrophy. As a consequence it is assumed that (all) plant based proteins have less potent anabolic properties when compared with animal based proteins. However, there is little theoretical background for such assumptions.

Study objective

Primary Objective: To provide evidence for the efficacy of wheat protein and wheat protein hydrolysate when compared with milk proteins as a dietary protein to stimulate postprandial muscle protein synthesis in vivo in healthy older humans. Secondary objective: To test whether ingesting a higher quantity (60 g) of wheat protein hydrolysate results in a muscle protein synthetic response similar to a meal-like amount (30 g) of whey protein.

Study design

double-blind, placebo-controlled intervention study

Intervention

A protein beverage (350 mL) containing 30 g of whey, casein, wheat protein, or wheat protein hydrolysate or 60 g of wheat protein hydrolysate will be consumed (n=12 per group).

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 18 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 an OGTT. Furthermore, we will ask the participants to fill out a medical questionnaire and record their food intake and activity 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 protein beverage (commercially available food product). 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 65 and 80 y
* BMI between 18.5 and 30 kg/m2

Exclusion criteria

Wheat allergy
Celiac disease
Lactose intolerance
Smoking
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
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-01-2014

Enrollment:	60
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	NCT01952639
CCMO	NL45958.068.13