The manipulation of dietary protein intake on the anabolic response in healthy young men

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STUDY 1: To investigate the impact of prior ingestion of a single high protein meal on the normal obligatory increase of muscle protein synthesis rates after protein intake and physical activity in healthy young men. STUDY 2: To investigate the...

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON38453

Source
ToetsingOnline

Brief title
PRO-ADAPT

Condition

- Other condition
- Protein and amino acid metabolism disorders NEC
- Muscle disorders

Synonym
protein turnover

Health condition

muscle metabolism

Research involving

Human

Sponsors and support

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

Intervention

Keyword: Protein synthesis, Resistance exercise, Skeletal muscle

Outcome measures

Primary outcome

skeletal muscle protein synthesis rates, expressed as fractional synthetic rate

(FSR) for both Study 1 and 2.

Secondary outcome

protein digestion and amino acid absorption kinetics for both Study 1 and 2.

Study description

Background summary

Protein intake stimulates muscle protein synthesis rates, and this effect is enhanced if physical activity is performed prior to food intake. Therefore, from the standpoint of maximizing (or maintaining) skeletal muscle mass, it is important to optimize the adaptive response to food intake. However, a paucity of information is available describing the effects of prior meal feedings, consisting of either high or low amounts of protein, on the subsequent meal-induced stimulation of muscle protein synthesis rates. Of note, it is necessary to determine the effects of ingesting a single high protein meal versus an *adaptation* that may occur after habitual consumption of high, or low, protein meals. An adaptation is certainly different in time-scale, but also may involve splanchnic and skeletal muscle adaptations that may further enhance, or decrease, the amino acid sensitivity of muscle protein synthesis rates after protein ingestion. Thus, we wish to assess both the immediate acute impact of a prior high protein meal on the subsequent stimulation of muscle protein synthesis rates after protein intake and physical activity (Study 1), and whether longer-term adjustments to the anabolic response to protein intake occurs after habitual consumption of high or low protein intakes for 14 days in

healthy young men (Study 2).

Study objective

STUDY 1: To investigate the impact of prior ingestion of a single high protein meal on the normal obligatory increase of muscle protein synthesis rates after protein intake and physical activity in healthy young men.

STUDY 2: To investigate the impact of a habitual (14 days) high or low protein diets on the muscle protein synthetic response to dietary protein ingestion

Study design

parallel, randomized (for both study 1 and 2)

Intervention

STUDY 1: Following unilateral resistance exercise, one group of subjects (n=12) will consume high protein beverages, and the second group (n=12) will consume isocaloric-matched carbohydrate beverages. The following morning, both groups of subjects will consume 20 g of whey protein.

STUDY 2: One group of subjects (n=12) will consume a high protein diet for 14 days and the second group (n=12) will consume a low protein diet for 14 days. The morning following the dietary intervention, both groups of subjects will consume 20 g of casein protein.

Study burden and risks

The risks involved in participating in this experiment are minimal. Insertion of the catheters is comparable to a blood draw and could result in a small hematoma. We will take 9 and 15 blood samples (8 mL) during the experimental infusion trials for Study 1 and 2, 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. Muscle biopsies will be taken under local anesthesia by an experienced physician, but may cause some minor discomfort for up to 24 h after completion of the procedure. The discomfort is comparable to muscle soreness or the pain that may be experienced after bumping into a table. In Study 1 participants will come to the university twice: 1 screening (2 hours) and 1 experimental trial lasting ~20 h, which also includes an overnight stay at the laboratory. During the screening, we will perform a DEXA scan. DEXA is a simple and non-invasive procedure. Three days prior to the experimental trials, participants will need to record their diet in detail for estimation of habitual protein intake. The labeled, non-radioactive amino acid tracers that will be infused intravenously are produced according to GMP standards and are safe for human use.

In Study 2 participants will come to the university for 2 main visits: 1 screening (2 hours) and 1 experimental trial lasting ~9 h. The same as study 1, during the screening we will perform a DEXA scan and three days prior to the experimental trials, participants will need to record their diet in detail for estimation of habitual protein intake. Between the screening and the experimental test day will be a 14 day period of complete dietary control and subjects will visit the university every 2 days to collect/return the prescribed food.
There is no direct benefit for the participants, only their contribution to scientific knowledge that will provide the evidence base for the prescription of exercise and nutritional strategies to improve the quality of life and health across the life-span.

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

Male
Aged between 18 and 35
BMI < 30

Exclusion criteria

Smoking
Allergies to milk proteins (whey or casein)
Vegetarians
Diagnosed GI tract diseases
Female
Arthritic conditions
A history of neuromuscular problems
Previous participation in amino acid tracer studies
Individuals on any medications known to affect protein metabolism (i.e. corticosteroids, non-steroidal anti-inflammatories, or prescription strength acne medications).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Placebo
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-01-2013
Enrollment:	28
Type:	Anticipated

Ethics review

Approved WMO Date:	01-05-2013
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	NL42878.068.12