Dietary strategies to augment post-prandial muscle protein accretion

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The objective of this study is to determine whether the intake of protein with extra leucine or extra carbohydrates added results in an improved muscle protein synthesis compared to the intake of only protein in elderly.

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

Summary

ID

NL-OMON34579

Source
ToetsingOnline

Brief title
Combined nutrient intake and muscle protein synthesis

Condition

- Muscle disorders

Synonym
loss of muscle mass, sarcopenia

Research involving
Human

Sponsors and support

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

Intervention

Keyword: carbohydrates, dietary protein, leucine, protein synthesis

Outcome measures

Primary outcome

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

Secondary outcome

Muscle enrichment of L-[1-13C]phenylalanine

Study description

Background summary

Young and elderly show differences in skeletal muscle mass. Aging is accompanied by a loss of skeletal muscle mass, which is a consequence of an imbalance between muscle protein synthesis and breakdown rates. Muscles consist of proteins. These proteins consist again of several building blocks: the amino acids. Due to our nutrition, which contains proteins and amino acids, building blocks are available for muscle protein synthesis. Our nutrition is an important stimulus of muscle synthesis. Previous research indicated that the anabolic stimulation is impaired in elderly after the intake of small amounts of protein or amino acids. In this study we would like to investigate whether the muscle protein synthesis in elderly is improved after addition of other nutrients to a standard protein drink. Two considered nutrients are carbohydrates and leucine. The main part of our meals consist of carbohydrates. The combination of protein and carbohydrates stimulates the release of the anabolic hormone insulin. This hormone stimulates the muscle protein synthesis. Intake of protein with carbohydrates could possilby increase the stimulation of muscle protein synthesis. Leucine is an essential amino acid which is also able to stimulate the muscle protein synthesis.
It has not yet been investigated whether the muscle protein synthesis in elderly is improved after the intake of a normal meal-like amount of protein in combination with leucine. Furthermore, it is unknown whether muscle protein synthesis is improved after the combined intake of a normal meal-like amount of protein with carbohydrates. In addition, it remains to be established whether the effect on muscle protein synthesis after a combined intake of protein and carbohydrates differs between young and elderly. This would possibly explain the differences in skeletal muscle mass.

Study objective

The objective of this study is to determine whether the intake of protein with extra leucine or extra carbohydrates added results in an improved muscle protein synthesis compared to the intake of only protein in elderly.

Study design

48 Males will participate in this study. Twelve males in the age of 70-85 years will receive a drink containing only protein. Twelve other males of the same age, will receive a protein drink with leucine added. Another 12 males will get a drink with the same amount of protein and extra carbohydrates added. In addition, a group of 12 young males (18-30 year) will get the same drink with protein and carbohydrates. Using the blood samples and muscle biopsies it will be possible to determine the muscle protein synthesis after intake of the test drink.
In total, this study consists of one pre-testing session of 4 hours and one test day which will take 6* hours, minimal 7 days after the pre-testing session. Due to the possible impact on the protein metabolism of a warm meal the day before the test day, the subjects receive a warm meal. In additon, we will ask them to complete a dietary record 48 hours before the test day.

Intervention

Intake of a protein drink with or without carbohydrates or leucine.

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 of a small local hematoma. This is the same for the muscle biopsy. The incision made for obtaining the muscle biopsy will heal completely within two days. Possibly, the subject might have a dull feeling in his leg when the effect of the anaesthetics is gone. The muscle biopsies will be performed by an experienced physician. The test beverages contain only normal nutritional ingredients dissolved in water, and will be flavoured with vanilla flavour; for this reason intake of the test drink does not form any health risks.
One CT scans will be performed on each subject. The level of radiation emitted during a CT scan is minimal since only single-slice scans will be taken and only measurements at the lower extremity (at the level of mid-thigh) will be performed. The exact radiation level is maximally 0.052 mSv.

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

Males
Age 70-85 years or age 18-30 years
BMI < 30 kg*m2

Exclusion criteria

Type II diabetes
All co morbidities interacting with mobility and muscle metabolism of the lower limbs
Use of anticoagulants; blood diseases, allergy for lidocain
Use of NSAIDs and acetylsalicylic acid
Patients suffering from PKU (Phenylketonuria)

Participation in any regular exercise program
Females

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):	14-01-2011
Enrollment:	48
Type:	Actual

Ethics review

Approved WMO

Date:	13-12-2010
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	NCT01239277
CCMO	NL34355.068.10