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Casein+ study: Dietary strategies to augment post-prandial muscle protein accretion

Submission date
14/09/2012

Recruitment status
No longer recruiting

Registration date
10/10/2012

Overall study status
Completed

Last Edited
16/06/2017

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
It is thought that the production of muscle protein after a meal in response to consuming protein and/or amino acids is impaired in the elderly compared to the young. Also, consuming carbohydrates at the same time increases secretion of the hormone insulin and increases muscle protein production in the young. However, it is unclear how the elderly respond to the combined intake of protein and carbohydrates. Likewise, consuming the amino acid leucine may also increase muscle protein production. Adding carbohydrate or leucine to protein may represent effective strategies to overcome the impaired muscle protein production in the elderly. This study consists of three substudies. The aim of the first study is to determine if the response to combined protein and carbohydrate intake is different between young and elderly men. The aim of the second study is to investigate whether consuming carbohydrate as well increases muscle protein production in elderly men. The aim of the third study is to examine whether consuming leucine increases muscle protein production in elderly men.

Who can participate?
Healthy male volunteers aged 18-30 and 70-85

What does the study involve?
Participants are randomly allocated to consume a drink containing either protein alone or protein in combination with carbohydrate or leucine. Blood samples and muscle biopsies (tissue samples) are collected to measure muscle protein production.

What are the possible benefits and risks of participating?
There are no benefits for participating in the study. There are minimal risks involved in participating in this study. The collection of blood samples is comparable to a normal blood draw and the only risk is a small local hematoma (a solid swelling of clotted blood). This is the same for the muscle biopsies. The cut made for taking the muscle biopsy is done by an experienced physician, following local anesthetics of the skin and muscle, and will heal completely. The test drinks contain dietary protein which is safe for human consumption.

Where is the study run from?
Maastricht University Medical Centre (Netherlands)

When is the study starting and how long is it expected to run for?
January 2011 to September 2012

Who is funding the study?
Maastricht University Medical Centre (Netherlands)

Who is the main contact?
Prof. Luc van Loon
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MEC 10-3-080

Study information

Scientific Title
Dietary strategies to augment post-prandial muscle protein accretion: a randomised controlled trial

Study objectives
1. The postprandial muscle protein synthetic response to the co-ingestion of protein and carbohydrates is attenuated in elderly when compared with the young.
2. The combined intake of protein and carbohydrates augments postprandial muscle protein

synthesis in elderly men when compared with protein intake alone.
3. The combined intake of protein and leucine augments postprandial muscle protein synthesis in elderly men when compared with protein intake alone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethics Committee, Maastricht University, 13/12/2010, ref: NL34355.068.10 / MEC 10-3-080

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Sarcopenia

Interventions
1. 20 g intrinsically labeled casein protein only in healthy elderly men
2. 20 g intrinsically labeled casein protein with 40 g of carbohydrate in healthy elderly men
3. 20 g intrinsically labeled casein protein with 2.5 g of leucine in healthy elderly men
4. 20 g intrinsically labeled casein protein with 40 g of carbohydrate in healthy young men

It was an acute intervention study thus a drink containing the above mentioned ingredients was only provided followed by the described measurements (multiple blood draws and three muscle biopsies)

Intervention Type
Other

Primary outcome measure
1. Muscle protein synthesis rate
2. Muscle biopsy at t=0 (before drink), t=120 and t=360 min

Secondary outcome measures

Plasma glucose, insulin, and amino acid concentrations. Blood draws at t=0 (before drink), 15, 30, 45, 60, 90, 120, 150, 180, 210, 240, 270, 300, 330 and 360 min

Overall study start date
01/01/2011

Completion date
15/09/2012

Eligibility

Key inclusion criteria
1. Males
2. Age 70-85 years or age 18-30 years
3. Body mass index (BMI) < 30 kg·m^2

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
85 Years

Sex
Male

Target number of participants
48

Key exclusion criteria
1. Type II diabetes
2. All co morbidities interacting with mobility and muscle metabolism of the lower limbs (e.g. arthrosis, arthritis, spasticity/rigidity, all neurological disorders and paralysis)
3. Use of anticoagulants, blood diseases, allergy for lidocain
4. Use of Nonsteroidal anti-inflammatory drugs (NSAIDs) and acetylsalicylic acid
5. Patients suffering from Phenylketonuria (PKU)
6. Participation in any regular exercise program

Date of first enrolment
01/01/2011

Date of final enrolment
15/09/2012

Locations

Countries of recruitment
Netherlands

Study participating centre
Universiteit Maastricht
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Sponsor information

Organisation
Maastricht University (Netherlands)

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Sponsor type
University/education

Website
http://www.maastrichtuniversity.nl/

ROR
https://ror.org/02jz4aj89

Funder(s)

Funder type
University/education

Funder Name
Maastricht University (Netherlands)

Alternative Name(s)
Maastricht University, UM

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Netherlands

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration