

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

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 10/10/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 16/06/2017	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

**Protocol serial number**  
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

## **Study type(s)**

Treatment

## **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(s)**

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

## **Key secondary outcome(s)**

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

## **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<sup>2</sup>

### **Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Upper age limit**

85 years

**Sex**

Male

**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

Maastricht

Netherlands

6200 MD

**Sponsor information****Organisation**

Maastricht University (Netherlands)

**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**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Not provided at time of registration