Protein feeding prior to sleep as a dietary strategy to improve post-exercise recovery and muscle mass in young and elderly men

Published: 07-02-2013 Last updated: 19-03-2025

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

Summary

ID

NL-OMON36991

Source ToetsingOnline

Brief title Protein feeding prior to sleep

Condition

- Protein and amino acid metabolism disorders NEC
- Muscle disorders

Synonym age-related muscle loss, sarcopenia

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit Maastricht **Source(s) of monetary or material Support:** Ministerie van OC&W,Top Institute Food and Nutrition (TIFN)

Intervention

Keyword: Dietary protein, Exercise, Muscle protein synthesis, Sleep

Outcome measures

Primary outcome

The main study endpoint is muscle protein synthesis (MPS) rate. In order to

determine the MPS, the following parameters

will be measured in blood and muscle tissue:

- Plasma phenylalanine, leucin and tyrosine concentration (expressed as µmol/L)
- Plasma verrijking van L-[ring-2H5]-pheenylalanine, L-[1-13C]-phenylalanine en

L-[ring-1-13C]-KIC (expressed as mole percent excess, MPE)

• Muscle protein bound enrichment of L-[

ring-2H5]-phenylalanine,L-[1-13C]leucine and L-[1-13C]-phenylalanine (expressed

as MPE)

• L-[1-13C]-phenylalanine enrichment of the muscle free amino acid pool

(expressed as

MPE)

Secondary outcome

Secondary endpoints include whole-body protein turnover, and protein digestion

and absorption kinetics. The following

parameters will be calculated:

• Total rate of phenylalanine appearance and disappearance (= protein turnover)

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- Exogenous phenylalanine rate of appearance
- Endogenous phenylalanine rate of appearance (=protein breakdown)
- Plasma availability of phenylalanine
- Plasma availability of amino acids
- Plasma glucose concentration
- Plasma insulin concentration
- Hunger and satiety
- Heartrate
- Sleep quality

Study description

Background summary

The regulation of muscle mass and function are critical during muscle growth and repair in both athletes as during advanced ageing, when the loss of muscle mass is a common phenomenom (sarcopenia). Sarcopenia has a large impact on the healthcare system causing an increased morbiditeit, hospitalization and/or institutionalization. The loss of muscle mass is caused by a combination of factors as a suboptimal food intake and a sedentary lifestyle. Aslo, an optimal nutritional status seems to be important during recovery in athletes. A disregulation of muscle protein turnover results in a disbalance between muscle protein synthesis and muscle protein breakdown. The intake of dietary protein is shown to have a positive impact on the synthesis of skeletal muscle proteins. Amino acids stimulates muscle protein synthesis and slows down muscle protein breakdown, resulting in a positive muscle protein net balance in both young and elderly. However, the timing of intake and the total amount influence muscle protein netto balance. An extra amount of dietary protein prior to sleep can increase the daily protein intake and could result in a positive protein balance. Moreover, it is unknown whether the intake of an amount of proteins prior to sleep stimulates muscle protein synthesis during the night. In the present study we investigte the impact of a single amount of protein with or without additional leucine on muscle protein synthesis during overnight sleep in healthy young and old men. Furthermore, we will assess digestion and absorption kinetics during sleep. The use of intrinsically labeled casein in combination with intravenous stable isotope infusion will allow us to assess de

novo muscle protein synthesis.

Study objective

The primary objective of this study is to investigate the effect of a meal-like amount of dietary protein prior to sleep on postprandial muscle protein synthesis in healthy young and elderly men, following exercise, during the night. Furthermore, as a secondary objective, we will assess digestion and absorption kinetics during sleep.

Study design

Double-blind randomized intervention study

Intervention

The young subjects will consume a testdrink of 400 ml with 0 gram, 30 gram intrinsically labelled casein of 30 gram intrinsically labelled casein + 2.0 g leucin, randomized after exercise or rest, prior to sleep. The elderly will consume a testdrink of 400 ml with 0 gram, 20 gram intrinsically labelled casein, 40 gram intrinsically labelled casein, or 20 gram intrinsic labelled casein + 1.2 gram leucin, randomized after exercise or rest, prior to sleep.

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. In total 5 (during screening 8 ml) and 15 blood samples (during test, 10 mL) will be taken. The total amount of blood draws (180 ml) 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 (evening and night, 14 hours). For the screening, participants have to be fasted, so they are not allowed to eat and drink (except for water) from 22h00 the evening before. Also, 2 days prior to the experimental trial participants should not perform any type of intense physical exercise, and 24 hours prior do not consume alcohol. During the screening a medical guestionnaire will be filled in, a DEXA scan and OGTT will be performed. Furthermore, the participants will be asked to consume distributed meals during the day of the trial and to fill out their food intake and an activity diary for 2 days prior to the experimental trial. During the experimental trial the subjects will stay overnight and prior/during their sleep we will collect muscle and blood

samples. All participants will consume a test beverage consisting of milk protein with or without additional leucine prior to sleep. The intrinsically labeled milk protein has been approved for human consumption and has been used in previous METC approved studies. With the use of both intrinsically labeled protein, intravenous stable isotope infusion of amino acids and blood and muscle samples de novo muscle protein synthesis from the ingested testdrink can be assessed during the night. There is no direct benefit for the participants, only their contribution to scientific knowledge and nutritional strategies that prevent muscle loss during recovery in athlethes and with advanced ageing in the elderly, which will be obtained from this study and used in the future.

Contacts

Public Universiteit Maastricht

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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 18 and 35, and 65 and 80 BMI < 30 kg/m2

Exclusion criteria

- Glucose intolerance
- Milk and/or fat intolerance
- Smoking
- Diagnosed GI tract diseases
- Arthritic conditions
- A history of neuromuscular problems

• Any medications known to affect protein metabolism (i.e. corticosteroids, non-steroidal antiinflammatories, or prescription strength acne medications)

- Use of anticoagulants
- Participation in exercise program
- Hypertension, high blood pressure above 140/90 mmHg
- Not participated in any strength training program within the last 3 months

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-01-2013
Enrollment:	144

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Type:

Anticipated

Ethics review	
Approved WMO Date:	07-02-2013
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

ID: 27673 Source: NTR Title:

In other registers

Register	ID
ССМО	NL42489.068.12
OMON	NL-OMON27673