Nocturnal protein supply during sleep as a dietary strategy to improve muscle mass in elderly

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To test the hypothesis that ingesting a nocturnal bolus of intact casein stimulates muscle protein synthesis in elderly.

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

Summary

ID

NL-OMON34886

Source
ToetsingOnline

Brief title
Nocturnal protein supply

Condition

- Other condition

Synonym
muscle loss, sarcopenia

Health condition

spieropbouw bij ouderdom

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: TIFN

Intervention

Keyword: elderly, muscle mass, Protein

Outcome measures

Primary outcome

The primary endpoint will be muscle protein synthesis. Muscle protein synthesis will be calculated by differences in plasma and muscle tracer enrichments. Phenylalanine and tyrosine enrichment in plasma samples and in the muscle free amino acid pool will be measured using gas chromatography-mass spectrometry, while the phenylalanine enrichment in muscle proteins will be measured with GC-combustion IRMS. We measure muscle protein synthesis after nocturnal protein ingestion by nasogastric tube.

Secondary outcome

None.

Study description

Background summary

Muscle loss, which begins after the age of 55 years, is one of the most important factors of disability in elderly people. This age-related loss of muscle mass and function, or sarcopenia, has substantial health consequences. The decline in lean body mass is accompanied by reduced physical performance, the loss of functional capacity and an increased risk of developing chronic metabolic diseases, like obesity and type 2 diabetes. Food intake and in particular the ingestion of protein or amino acids has been shown to be a powerful stimulus to promote net muscle protein anabolism by providing ample amino acids as precursors for protein assembly. However, dietary protein/amino

acids should not be regarded as merely the building blocks of body tissue proteins. A growing body of evidence indicates that essential amino acids (EAA), and leucine in particular, function as potent nutritional signalling molecules with an active regulatory role in muscle protein metabolism. It is believed that EAA are likely to be responsible for the amino acid induced stimulation of muscle protein synthesis.

So far, only few studies have focused on overnight muscle protein synthesis. Stimulating muscle protein synthesis during sleep, might augment muscle hypertrophy, increase mitochondrial mass, and/or improve muscle tissue repair.

Overall, the goal of this proposal will be to provide further insight into the responsiveness of the muscle protein synthetic machinery to food intake at night in relation to age.

The aim of this proposal is to investigate the nocturnal muscle protein synthesis rates in elderly men in response to a meal-like protein bolus at night.

Study objective

To test the hypothesis that ingesting a nocturnal bolus of intact casein stimulates muscle protein synthesis in elderly.

Study design

At 18.00 h subjects will report to the laboratory, where a standardized meal will be provided. Before 19.00 h, a Teflon catheter will be inserted into an antecubital vein for starting a primed, continuous infusion of stable isotope labelled phenylalanine and tyrosine. A second Teflon catheter will be inserted in the contra lateral hand vein for arterialised blood sampling. Blood will be arterialised by placing the hand in a hot-box and a resting/background blood sample will be drawn. At 19.00 h, tracer infusion will be started. At 21.00 a commercially available nasogastric stomach feeding catheter (Bengmark, Flocare, Zoetermeer, the Netherlands) will be inserted by a physician. The catheter will be placed with the tube tip located in the stomach, according to the manufacturers instructions (see attachment and MEC NL24018.068.08). This catheter will be used to administer protein beverages during sleep. At 23.00 h the first muscle biopsy will be taken. Subsequently, subjects prepare to sleep at 0:00 h. This will be followed by a sleeping period of 7 h. The second muscle biopsy will be obtained at 7.00 h. Blood samples (8ml) will subsequently be taken from the arterialised hand vein at t = -420, -360, -300, -240, -180, -120, -60, 0, 30, 60, 90, 120, 180, 240 and 300 minutes. Muscle biopsies will be taken at t = -3 h, and 5 h after protein ingestion by nasogastric tube.

Intervention

At 02.00 h, half of the subjects will receive a bolus of protein beverage by their nasogastric tube. The same protein as has been used previously [MEC 07-3-086], will be used in this study. Subjects receive a beverage volume of 500 ml water with the addition of 40 g intact casein protein (CAS). L-[1-13C]phenylalanine labelled milk proteins are produced in collaboration with Dr Boirie (Clermont-Ferrand, France) using registered cattle for milk production applying quality process #0000640 in accordance with standard NF V 01-005. Milk proteins will be processed to obtain purified CAS by DSM Food Specialties (Delft, The Netherlands). During the processing of the milk, total plate count and several tests for micro-organisms will be performed (B. cereus, St. aureus, coliforms, moulds yeast, salmonellae and lysteria) to assure that no contamination occurs during processing. The intact casein protein will be tested according to DSM*s manufacturing specifications conforms to the performance typical for this grade and product description, before clearance will be given for use in human subjects. Beverages will be uniformly flavoured by adding 0.2 g sodium-saccharinate solution (25% w/w), 1.8 g citric acid solution (50% w/w) and 5 g of cream vanilla flavour for each litre of beverage. Drinks will be prepared according to Standard Operating Procedure #RM001, routinely applied in the kitchen of the departments of Human Biology and Movement Sciences the evening before each test. After preparation, drinks will be stored at 4 ºC until utilization the next morning.

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 drawn and the only risk is of a small local haematoma. This is the same for the muscle biopsy. The incision made for obtaining the muscle biopsy (performed by an experienced physician) will heal completely. The labelled amino acid tracers applied in this experiment are not radioactive and are completely safe. The test beverage contains intrinsically labelled dietary protein, which is safe for human consumption (see attachment) and has been used in previous studies [MEC 07-3-086]. The drinks are made from normal nutritional ingredients and do not impose any health risks.

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
65-80 yr of age
no medication
BMI < 30 kg/m2

Exclusion criteria

Comorbidities associated with muscle metabolism

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-06-2010
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	04-06-2010
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
CCMO	NL30455.068.09