Dietary strategies to promote muscle protein anabolism in the elderly

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

Summary

ID

NL-OMON31675

Source
ToetsingOnline

Brief title
Dietary interventions for muscle mass

Condition

- Other condition
- Muscle disorders

Synonym
loss of muscle mass, sarcopenia

Health condition

preventie sarcopenie

Research involving
Human

Sponsors and support

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

Intervention

Keyword: aging, dietary protein, muscle, protein synthesis

Outcome measures

Primary outcome

All interventions will affect muscle protein synthesis. With the application of amino acid tracer methodology we are able to determine muscle protein synthesis.

Secondary outcome

Differences in rate of uptake/absorption for the intestine using the application of intrinsically milk proteins.

Study description

Background summary

Aging is associated with the loss of lean muscle mass, termed sarcopenia. 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. However this anabolic response following a meal-like protein bolus seems to be blunted in the elderly as compared to young adults. It has been speculated that this blunted protein synthetic response to meal ingestion prevents net muscle protein accretion throughout the day, leading to the structural loss of skeletal muscle tissue over the years. An important factor that has been suggested to contribute to the blunted anabolic response to meal ingestion in the elderly is an impaired and/or delayed protein digestion. It is evident that the quantity, as well as the quality of the ingested protein, i.e. its digestibility and its amino acid composition, strongly modulate protein metabolism. Besides nutrition, exercise has been shown to be a powerful stimulus to promote net muscle protein anabolism and/or muscle tissue remodeling. The nutrition effect on muscle protein synthesis is relatively

transient and acts on a global whole body level rather than on a specific skeletal muscle level. Physical activity stimulates a longer-term adaptive response, which may stimulate muscle protein synthesis for up to 48 h. So providing nutrition after physical activity creates a large positive net muscle protein balance, and leads to an increase in muscle mass. However the available data in humans is scarce whether a period of physical activity prior to a meal-like protein intake, an increase in protein intake, or an improved quality of the protein bolus can overcome the blunted anabolic response in the elderly.

Study objective

The first aim of this proposal is to investigate the post-prandial muscle protein synthesis rates in young and elderly men in response to a meal-like protein bolus after a period of rest or physical activity (study A). The rest trial (REST) will act as a proof-of-principle study to examine the blunted protein synthetic response in the elderly, and as a control trial in comparison with the exercise trial (EXC) to establish the surplus value of physical activity prior to protein intake on muscle protein synthesis.
The second aim of this proposal is to determine the surplus value of an increased quantity of the ingested protein bolus (study B). Large amounts of protein (40 and 60 g) will be compared to a meal-like amount of protein (20 g) as a means to maximize plasma amino acid availability and/or to stimulate muscle protein anabolism.
The third aim of this proposal is to study the differences in quality of the ingested protein bolus (study C). Instead of significantly increasing the quantity of the protein bolus, we will also apply a more practical approach to augment skeletal muscle protein synthesis rates; modifying the digestibility or amino acid composition of a meal-like protein bolus. With the concept of slow and fast digestible proteins in mind, we will compare a meal-like bolus of *slow* intact protein to a meal-like bolus of its *fast* hydrolysate and to a meal-like bolus of *fast* intact protein. Furthermore, we will compare a meal-like bolus of intact protein with or without the addition of a small amount of the amino acid leucine.

Study design

Previous studies have contributed significantly to our current knowledge on the post-prandial muscle protein synthesis response, but due their methodology, were unable to mimic the normal physiological process of protein intake, digestion and the muscle protein synthetic response following on it. Only with the use of an intrinsically labeled protein source will we be able to clearly mimic the normal physiological process of meal ingestion and measure the rate of protein digestion. We have produced an intrinsically labeled protein and used it successfully in a recent human intervention study (MEC 06-3-064). Furthermore will we combine the use of these intrinsically labeled milk proteins with a labeled amino acid infusion protocol as previously described in

MEC 02-060, MEC 03-090, MEC 05-028 and MEC 06-3-064. This offers us a powerful tool and a unique method to quantify the in vivo response of protein intake on skeletal muscle protein synthesis rates.

Intervention

Study A: Moderate physical exercise versus rest prior to protein intake
Study B: Protein intake differing in quantity
Study C: Protein intake differing in quality

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 hematoma. This is the same for the muscle biopsy. The incision made for obtaining the muscle biopsy will be done by an experienced physician and will heal completely. The labeled amino acids tracers applied in this experiment are not radioactive and are completely safe. De test beverages are made from normal nutritional ingredients and for this reason do not form any health risks. The exercise protocol exists of cycling and resistance-type exercise on a low to moderate intensity which may lead to some muscle soreness in the upper legs the next day.

• General screening 3 h (all the subjects in all three studies A, B, C)
• Additional screening 1 h (only for the subjects in study A)
• Trial day 8 h (all the subjects in all three studies A, B, C)

All subjects of study A will visit the University for a total time of 12 h. All subjects of studies B and C will visit the University for a total time of 11 h.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

In study A, non-obese male subjects (BMI <27) between the age of 18-30 yrs and 70-85 yrs will be selected. In studies B and C, non-obese male subjects (BMI <27) between the age of 70-85 yrs will be selected.

Exclusion criteria

Exclusion criteria are: type II diabetes or other known diseases, use of medication, female, other ages or BMI than indicated above, participation in any regular exercise program.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2007
Enrollment:	132
Type:	Actual

Ethics review

Approved WMO Date:	26-11-2007
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	30-06-2008
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	13-10-2008
Application type:	Amendment
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	NCT00557388
CCMO	NL19966.068.07