Casein in milk as a functional ingredient for the prevention of sarcopenia

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To compare the digestibility, bioavailability and subsequent muscle protein synthetic response to casein, with casein protein provided in an isolated manner versus casein in a milk matrix, in healthy elderly subjects

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

Summary

ID

NL-OMON40261

Source
ToetsingOnline

Brief title
Casein in milk

Condition

- Other condition

Synonym
Loss of muscle mass, sarcopenia

Health condition

spiermetabolisme

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Casein, Elderly, Milk, Muscle

Outcome measures

Primary outcome

Primary endpoint: Muscle protein synthetic rate, expressed as fractional

synthetic rate (FSR).

Secondary outcome

Secondary endpoints: Rate of protein digestion and absorption and whole body

protein balance

Study description

Background summary

The progressive loss of skeletal muscle mass with aging, or sarcopenia, has a major impact on our healthcare system due to increased morbidity and greater need for hospitalization and/or institutionalization. One way to prevent skeletal muscle loss is to improve dietary intake of the elderly.
The ingestion of milk proteins is known to strongly stimulate muscle protein synthesis and inhibits protein breakdown, resulting in a positive net protein balance and, as such net muscle protein accretion. This anabolic effect clearly depends on the quality and the quantity of the protein source. The major proteins in bovine milk are casein (~80%) and whey protein (~20%). In their isolated forms, these proteins greatly differ in their digestion and absorption kinetics. Isolated whey protein has been characterized as a rapidly digested protein leading to a pronounced, rapid, but transient peak in plasma amino acid levels. On the other hand, isolated casein is a slowly digested protein that results in a slower, moderate, but more prolonged increase in plasma amino acid availability when compared to whey protein. When casein enters the stomach and is brought to a pH of 4.6 or lower, casein precipitates, whereas whey protein

remains in solution and does not clot. At present, casein is regarded as a less anabolic protein in the elderly, due to its slower digestion and absorption. However, these studies have all provided their subjects with isolated casein. It is currently unknown how casein behaves when it is ingested in its natural form as a constituent of whole bovine milk. There are several indications that casein may behave quite differently when it is ingested within the matrix of normal milk. Besides whey protein and casein, normal skimmed milk also contains lactose, salts, minerals and vitamins. These other components may modulate gastric pH and/or emptying and thus the bioavailability of casein derived amino acids and therefore the subsequent post-prandial muscle protein synthetic response. The results from this study will provide important insight in the development of novel nutritional intervention strategies to counteract the age-related loss of muscle mass.

Study objective

To compare the digestibility, bioavailability and subsequent muscle protein synthetic response to casein, with casein protein provided in an isolated manner versus casein in a milk matrix, in healthy elderly subjects

Study design

Randomized, single blind, parallel study

Intervention

one group (n=16) will consume a test beverage of 600 mL containing 20 g of intrinsically labeled casein in water, and the other group (n=16) will consume a beverage of the same volume containing 20 g of intrinsically labeled casein in milk matrix

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 draw and the only risk is a small local hematoma. This is also true for muscle biopsies. Muscle biopsies will be taken through a small (5 mm) incision, following local anesthetics of the skin and muscle fascia, and will heal completely. Muscle biopsies will only be obtained by an experienced physician. The labeled, non-radioactive amino acids tracers that will be infused intravenously are produced according to GMP standards and are safe for human use.

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

- Males
- Aged between 65-85 years
- Healthy, recreationally active (self-reported total of 2-4 hours of walking and/or light cycling (for transportation purposes) per week)
- BMI < 30 kg/m2
- No mobility limitations (i.e. able to perform all activities associated with daily living in a independent manner).

Exclusion criteria

- Female

- Smoking
- Allergies to milk proteins (whey or casein)
- Arthritic conditions
- Over the counter antacids
- Diabetes mellitus type 1 and type 2 (fasting blood glucose above 6.1 mmol/L and and/or 2 hour OGTT glucose level higher than 7.8 mmol/L)
- A history of neuromuscular problems
- Individuals on any medications known to affect protein metabolism (i.e. corticosteroids, non-steroidal anti-inflammatories, or prescription strength acne medications).
- Participation in any structured regular exercise program
- Chronic use of gastric acid suppressing medication or anti-coagulants
- Unstable weight over the last three months
- Pathologies of the gastrointestinal tract

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-04-2014
Enrollment:	32
Type:	Actual

Ethics review

Approved WMO

Date:	14-03-2014
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	NL47390.068.13