Anabolic properties of BCKA and BCAA in vivo in older men

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To provide evidence for the efficacy of Branched Chain Keto Acids (BCKA) and Branched Chain Amino Acids (BCAA) when compared with milk proteins to stimulate postprandial muscle protein synthesis in vivo in healthy older humans.

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

Summary

ID

NL-OMON42909

Source
ToetsingOnline

Brief title
Keto study

Condition

- Other condition
- Muscle disorders

Synonym
loss of skeletal muscle mass, Sarcopenia

Health condition

Het onderzoek zal worden uitgevoerd in gezonde proefpersonen

Research involving
Human

Sponsors and support

Primary sponsor: Evonik Industries
Source(s) of monetary or material Support: Bedrijf (Evonik Industries)

Intervention

Keyword: Amino acids, Keto acids, Muscle, Protein

Outcome measures

Primary outcome

Primary study parameters include post-prandial plasma amino acid availability

and myofibrillar muscle protein synthesis rates.

Secondary outcome

Secondary study parameters include whole-body protein synthesis, breakdown,

oxidation, and net balance.

Study description

Background summary

Protein and/or essential amino acids are important for stimulating muscle protein synthesis (MPS) rates and inhibiting muscle protein breakdown. The anabolic properties to protein feeding can be increased by the co-ingestion of free leucine, thereby increasing the amount of dietary protein derived amino acids that are used for de novo muscle protein synthesis. Consequently branched chain amino acid (BCAA) supplementation or fortification can be used to increase MPS. However, supplementing with high amounts of protein and/or BCAA, necessary to stimulate MPS, can be harmful for patients suffering from for example Chronic Kidney Disease (CKD). Supplementation with branched chain keto acids (BCKA) may be of particular relevance in these conditions as these keto analogues do not provide nitrogen (N) and may help to reduce metabolic workload of liver and kidneys. However, it remains to be established whether BCAA and BCKA can be useful in stimulating MPS in vivo in humans.

Study objective

To provide evidence for the efficacy of Branched Chain Keto Acids (BCKA) and

Branched Chain Amino Acids (BCAA) when compared with milk proteins to stimulate postprandial muscle protein synthesis in vivo in healthy older humans.

Study design

Randomized double-blind, parallel design study.

Intervention

A beverage (300 mL) containing 6 g of BCAA, 6 g of BCKA- or 30 g of milk protein will be consumed (n=15 per group).

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. We will take 5 and 17 blood samples (10 mL) during the screening and experimental trial respectively. The total amount of blood we draw 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 (entire day). For both the screening and the experimental trial, participants have to be fasted, so they are not allowed to eat and drink (except for water) from 22h00 the evening before. Also, 3 days prior to the experimental trial participants should keep their diet as constant as possible, do not perform any type of intense physical exercise, and do not consume alcohol. During the screening we will perform a DEXA and an OGTT. Furthermore, we will ask the participants to fill out a medical questionnaire and record their food intake and activity for 2 days prior to the experimental trial. During the experimental trial, we will collect muscle and blood samples, and participants have to consume a beverage containing protein (Milk), amino acids (BCAA) or keto acids (BCKA). There is no direct benefit for the participants, only their contribution to scientific knowledge and nutritional strategies that prevent muscle loss in the elderly, which will be obtained from this study and used in the future.

Contacts

Public
Evonik Industries

Rellinghauser Straße 1-11

Essen 45128
DE
Scientific
Evonik Industries

Rellinghauser Straße 1-11
Essen 45128
DE

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Healthy males
Age between 65 and 80 y
BMI between 18.5 and 30 kg/m2

Exclusion criteria

Lactose intolerance
Smoking
Diabetes
Diagnosed GI tract diseases
Arthritic conditions
A history of neuromuscular problems
Any medications known to affect protein metabolism (i.e. corticosteroids, non-steroidal anti-inflammatories, or prescription strength acne medications).
Use of anticoagulants
Participation in exercise program
Hypertension, high blood pressure that is above 140/90 mmHg

Females (in order to have a more homogenous group)

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-01-2017
Enrollment:	55
Type:	Actual

Ethics review

Approved WMO

Date:	05-10-2016
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	NL58952.068.16