The influence of leucine supplementation on body composition and muscle characteristics in elderly, type 2 diabetes patients

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To study the influence of ingestion of additional leucine on body composition and muscle characteristics in elderly, type 2 diabetes patients.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Interventional

Summary

ID

NL-OMON32082

Source
ToetsingOnline

Brief title
Leucine supplementation in elderly, type 2 diabetes patients

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Muscle disorders

Synonym
type 2 diabetes

Research involving
Human

Sponsors and support

Primary sponsor: Top Institute Food & Nutrition

Source(s) of monetary or material Support: TIFN

Intervention

Keyword: elderly, leucine, long term, type 2 diabetes

Outcome measures

Primary outcome

Body composition and muscle characteritics will be compared on 0, 3 and 6

months of the intervention.

Secondary outcome

Maximal strength

Lipid profile

Cognitive function

HbA1c

Plasma glucose responses

Study description

Background summary

Aging and type 2 diabetes are associated with a decrease in muscle synthesis, which is one of the main causes for decreased muscle mass and muscle function. This process leads to a decreased performance, decreased ability to live independently, increased risk to become obese, osteoporosis and cardiovascular diseases.

To increase muscle protein synthesis it is essential that building blocks from nutrition are available in the body. Recent research has shown that amino acid supplements can lead to an increase in muscle protein synthesis. The increased muscle protein synthesis after amino acid intake can lead to an increase of muscle mass and an improved performance of the muscles. At the moment there are indications that certain amino acids after intake have a stimulating effect on insulin secretion. This could have a positive effect for type 2 diabetes, because the intake of certain amino acids could improve plasma glucose respons.

In the present study we will investigate to what extent the intake of leucine (an essential amino acid) supplements can influence body composition, muscle characteristics and plasma glucose respons in elderly, type 2 diabetes patients.

Study objective

To study the influence of ingestion of additional leucine on body composition and muscle characteristics in elderly, type 2 diabetes patients.

Study design

2 groups of elderly, type 2 diabetes patients will perform a 6 month placebo controlled trial with 2.5 g additional leucine or placebo supplementation per meal.
Body composition and muscle characteristics will be compared at 0, 3 and 6 months time of the intervention.

Intervention

A 6 month placebo controlled trial. During these 6 months 30 subjects will take leucine supplementation en 30 subjects will take placebo supplements. Daily the subjects will take 7.5 g leucine/placebo (2.5 g/meal).

Study burden and risks

At the site of the catheter a hematoma could occur. This is the same for the muscle biopsy. The muscle biopsy is performed by an experienced physician. The incision made for obtaining the muscle biopsy will heal completely.
An ECG will be performed, during rest and exercise, before inclusion in the study population, this to exclude cardiovascular problems.
The level of radiation emitted during a DEXA scan is very low, so this is harmless.
The radiation from the CT scan is negligible because only one image is taken and this on 0, 3 and 6 months of the intervention.
The ingested bolus of glucose is comparable with a commercial sport nutrition drink. The ingested leucine/proteins are part of a normal diet as a precursor for protein synthesis and impose no risk.
To minimize the risk for muscle soreness and/or muscle injuries, an experienced invesitigator will supervise all exercise tests

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

elderly men
older then 65 years of age
type 2 diabetes

Exclusion criteria

impaired renal or liver function, cardiac disease, hypertension, diabetes complications, and exogenous insulin therapy

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):	22-07-2008
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	10-06-2008
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
ClinicalTrials.gov	NCT00643773
CCMO	NL22644.068.08