

The impact of gender, inactivity, and obesity on muscle mass building and muscle mass maintenance.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23856

Source

Nationaal Trial Register

Brief title

The GIO study

Health condition

aging, muscle protein synthesis, gender, inactivity, obesity

Sponsors and support

Primary sponsor: Maastricht University

Source(s) of monetary or material Support: Top Institute Food and Nutrition (TIFN)

Intervention

Outcome measures

Primary outcome

Basal and postprandial muscle protein synthesis rates.

Secondary outcome

Study description

Background summary

The main objective of the present project is to assess the impact of gender, physical inactivity, and obesity on basal and postprandial muscle protein synthesis rates. This will be investigated in three different substudies:

Substudy A: The impact of gender on basal and postprandial muscle protein synthesis.

Substudy B: The impact of physical inactivity on basal and postprandial muscle protein synthesis.

Substudy C: The impact of obesity on basal and postprandial muscle protein synthesis.

Basal and postprandial muscle protein synthesis will be studied by means of stable isotope methodology and intrinsically labeled milk proteins.

Study objective

1. The postprandial muscle protein synthesis rate is smaller in females as compared with males.
2. Short-term physical inactivity reduces basal and postprandial muscle protein synthesis rates.
3. Basal and postprandial muscle protein rates are blunted in obese as compared to lean individuals.

Study design

Subjects participate in a screening session and a single test day. During the test day, frequent blood samples and muscle biopsies will be taken for the assessment of basal and postprandial muscle protein synthesis. Basal muscle protein synthesis will be assessed over a 2-hour period, and postprandial muscle protein synthesis will be assessed over a 5-hour period.

Intervention

Substudy A: During a single test day, subjects will undergo continuous intravenous tracer infusions of labelled amino acids, and subjects ingest a beverage containing 25 gram intrinsically labelled milk protein. Blood plasma samples and muscle biopsies will be collected during the test day.

Substudy B: Five days of unilateral knee immobilization will be followed by a single test day. During the test day, subjects undergo continuous intravenous tracer infusions of labelled amino acids, and subjects ingest a drink containing 25 gram intrinsically labelled milk protein. Blood plasma samples and muscle biopsies will be collected during the test day.

Substudy C: During a single test day, subjects undergo continuous intravenous tracer infusions of labelled amino acids, and subjects ingest a drink containing 25 gram intrinsically labelled milk protein. Blood plasma samples and muscle biopsies will be collected during the test day.

Contacts

Public

Jan-Willem Dijk, van
Maastricht
The Netherlands

Scientific

Jan-Willem Dijk, van
Maastricht
The Netherlands

Eligibility criteria

Inclusion criteria

Subgroup A:

-Males and females

-Aged between 30-55 years

-BMI 19-25 kg/m²

Subgroup B:

-Male

-Aged between 18-35 years

-BMI 19-30 kg/m²

Subgroup C:

-Male

-Aged between 30-55 years

-BMI >35 kg/m²

Exclusion criteria

Subgroup A:

-Currently smoking cigarettes or tobacco

-Allergies to milk proteins (whey or casein)

-A history of neuromuscular problems

-Diagnosed impaired renal (kidney stones, nephritis, nephritic syndrome, end-stage renal disease) or liver function (acute or chronic hepatitis, alcoholic liver disease, liver cirrhosis)

-Use of medications known to affect digestion and/or absorption (antacids, H₂-receptor blockers, proton pump inhibitors, NSAID's) 7 days prior to the experimental test-day.

-Use of anticoagulants, blood diseases, allergy for lidocain

-Use of medications known to affect protein metabolism (i.e. corticosteroids, non-steroidal anti-inflammatories, or acne medications).

-Type 2 diabetes (exclusion when: fasting glucose level >7.0 mmol/L, or 2-h glucose level >11.1 mmol/l, or HbA1c $>6.5\%$).

Subgroup B:

-Currently smoking cigarettes or tobacco

-Allergies to milk proteins (whey or casein)

-Arthritic conditions

-History of neuromuscular problems

-History of deep venous thrombosis (DVT) or pulmonary emboli (PE).

-Diagnosed impaired renal (kidney stones, nephritis, nephritic syndrome, end-stage renal disease) or liver function (acute or chronic hepatitis, alcoholic liver disease, liver cirrhosis)

-Use of medications known to affect digestion and/or absorption (antacids, H-2-receptor blockers, proton pump inhibitors, NSAID's) 7 days prior to the experimental test-day

-Use of anticoagulants, blood diseases, allergy for lidocain

-Use of medications known to affect protein metabolism (i.e. corticosteroids, non-steroidal anti-inflammatories, or acne medications).

-Type 2 diabetes (HbA1c $>6.5\%$).

Subgroup C:

-Allergies to milk proteins (whey or casein)

-A history of neuromuscular problems

-Diagnosed impaired renal (kidney stones, nephritis, nephritic syndrome, end-stage renal disease) or liver function (acute or chronic hepatitis, alcoholic liver disease, liver cirrhosis)

-Use of anticoagulants, blood diseases, allergy for lidocain

-Use of medications known to affect protein metabolism (i.e. corticosteroids, non-steroidal anti-inflammatories, or acne medications).

-Diagnosed type 2 diabetes, and/or use of blood glucose lowering medication.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-03-2013
Enrollment:	62
Type:	Anticipated

Ethics review

Positive opinion	
Date:	04-07-2013
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 41407
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL3898
NTR-old	NTR4060
CCMO	NL42551.068.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON41407

Study results

Summary results

N/A