Measure protein metabolism via a breath test.

No registrations found.

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

Summary

ID

NL-OMON25304

Source
NTR

Brief title
POS

Health condition

If the protein oxidation breath test has discriminative powers, the breath test could be applied as a screening tool in people who are of risk at having malnutrition. Currently, the breath test will be tested on healthy volunteers.

Intervention

Outcome measures

Primary outcome

Total 13C-protein oxidation measured by the breath test over 5,5 hours.

Secondary outcome

4-day food diaries. 1 for baseline measurement of habitual energy and protein intake. The other three for the different interventions.

24-hour urine collection for measuring urea (protein intake) and creatinine (muscle mass)

Study description

Background summary

Researching protein oxidation in a non-invasive way could be an interesting approach to perform more research on protein metabolism. Our 30 gram 13C-protein breath test enables us to measure protein oxidation over 5,5 hours. With the knowledge that protein metabolism consists mainly of primarily incorporation of amino acids and secondarily oxidation of surplus amino acids we can make statements about total protein metabolism. In this trial, we will measure the effects of subjects' habitual diets (rich in protein, average 1.15 g protein/kg bw/day) versus a 4-day low protein diet (0.25 g protein/kg bw/day) on the protein oxidation measured bythe breath test performed on the fifth day. We expect to measure less of the 30 g protein being oxidized after a 4-day low protein diet compared to their habitual diet, similar to results aquired during our pilot experiment.

Study objective

Protein metabolism consists of amino acid incorporation and amino acid oxidation. We have developed a breath test which is able to measure the oxidation of ingested 13C-protein. We hypothesize that a diet low in protein before the breath test will result in a shortage of protein the body. During the test we expect to measure less 13C-protein to be oxidized compared to a normal protein diet.

Study design

Baseline breath sample at t = -5 minutes
30 g 13C-protein in 500 ml water consumption at t = 0 (09:15)
Breath samples every ten minutes starting at 09:25 untill 14:45

Intervention

4 days of high protein diet (1,35 g protein / kg bodyweight /day) at habitual energy intake followed on day 5 by the protein oxidation breath test.

4 days of medium protein diet (0,8 g protein / kg bodyweight /day) at habitual energy intake followed on day 5 by the protein oxidation breath test.

4 days of low protein diet (0,25 g protein / kg bodyweight /day) at habitual energy intake followed on day 5 by the protein oxidation breath test.

Contacts

Public
Hanzeplein 1 UMCG

Gerlof Reckman
Groningen 9713 GZ
The Netherlands
06 57 27 54 11
Scientific
Hanzeplein 1 UMCG

Gerlof Reckman
Groningen 9713 GZ
The Netherlands
06 57 27 54 11

Eligibility criteria

Inclusion criteria

Healthy volunteers:

Male

Age between 18 - 30

Exclusion criteria

- Disease and/or being medically treated (e.g. diabetes mellitus)

- Milk (protein) allergy or intolerance

- Smoking

- Drug use

- Alcoholism, and no alcohol during the 4-day diets

- Waist circumference ≥102 cm

- Vegetarian

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2016
Enrollment:	16
Type:	Anticipated

Ethics review

Positive opinion

Date:	19-09-2016
Application type:	First submission

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
NTR-new	NL5921
NTR-old	NTR6101
Other	METc commissie UMCG : METc 2016.144

Study results