The influence of different levels of protein diet on protein oxidation measured by 13CO2 breath test

Published: 21-07-2016
Last updated: 17-04-2024

The aim of this study is to determine whether our 13CO2 breath test is discriminative for different protein diets in healthy young volunteers.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Protein and amino acid metabolism disorders NEC
Study type	Interventional

Summary

ID

NL-OMON43001

Source
ToetsingOnline

Brief title
Protein oxidation study

Condition

- Protein and amino acid metabolism disorders NEC

Synonym
protein oxidation

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W,HanzeNutrition BV

Intervention

Keyword: breath test, protein oxidation, protein status, stable isotopes

Outcome measures

Primary outcome

The total protein oxidation measured during the breath test of the different

protein diets will be used to answer our research question.

Secondary outcome

Not applicable.

Study description

Background summary

Malnutrition is a major negative determinant for the clinical outcome of patients. The hallmark of malnutrition is disturbed protein metabolism, i.e. increased oxidation of amino acids and decreased incorporation of amino acids, which leads to loss of muscle mass.
Current detection of malnutrition relies on clinical signs, such as weight loss, or on identification of risk factors, such as poor dietary intake, and as such provides the basis for dietary intervention. To initiate, guide and evaluate (dietary) intervention, it would be highly useful to be able to monitor the derangements in protein oxidation directly, but until recently a bedside tool to assess protein oxidation was not available.
A recently developed non-invasive low naturally enriched 13C-protein 13CO2 breath test has shown to be able to quantify the oxidation rate of ingested low naturally 13C-enriched milk-proteins derived amino acids directly. This breath test seems valuable for patient populations, because it elicits the possibility to develop a simple bedside monitoring tool for quantification of amino acid oxidation and amino acid incorporation. The underlying principle of the test is: 13C-protein + O2 --> 13CO2 + H2O.
In our pilot experiments we have found clear differences in the oxidation kinetics of whey and casein (both repeated 4 times within 1 person). Whey is oxidized faster than casein. This corresponds with measurements by Boirie et al. 1997 in which they measured the arrival of amino acids of whey and casein in blood. A different pilot experiment showed that a 3-day very low protein diet (repeated 4 times within 1 person) results in less oxidation of protein compared to a habitual diet rich in protein (repeated 6 times within 1 person),

which shows that the breath test has discriminative powers.

Study objective

The aim of this study is to determine whether our 13CO2 breath test is discriminative for different protein diets in healthy young volunteers.

Study design

Crossover study.

Intervention

Controlled isocaloric dietary protein intake for 4 days at different levels of intake: 0.25 g protein/kg/day, 0.8 g protein/kg/day and 1.35 g protein/kg/day followed on the fifth day by consumption on of 30 g of naturally low enriched 13C-milk protein, which is produced by NIZO (Dutch Institute for Dairy Research). After consumption, breath samples will be taken every 10 minutes for a total duration of 5.5 hours. All subjects will participate in all diet conditions in a determined sequence separated by at least 1 week between each diet. Dietsequence: 1.35, 0.80, 0.25 g protein/kg/day.

Study burden and risks

The subjects will keep a food diary for 4 days in order to collect data on their habitual diet. On the fourth day, the subjects will collect 24-hour urine in which urea and creatinine will be measured, which will serve as a measure for muscle mass. Age will be noted. Physical parameters such as height, weight, body mass index, waist-circumference and fat-free mass will be measured and/or determined. Fat-free mass will be measured by bioelectrical impedance, which is a non-invasive method. Body surface area will be calculated upon height and weight, using the formula described by Haycock et al. Taken together, these will serve as their baseline values. The subjects will follow a 4-day protein isocaloric diet three times, using three levels of protein. The subjects will collect 24-hour urine every day during each 4-day diet.

During the 4-day diets, subjects will refrain from all 13C enriched products (e.g. maize, sugar cane and pineapple), alcohol, exercise. On the fourth day, subjects will start fasting from 22:00 until 09:15 the following morning. The fifth day will be the day of the breath test in which subjects give breath samples by exhalation through a drinking straw into a glass (12 ml) container. The test drink, which is part of the breath test, will consist of 30 g of milk protein dissolved in 500 ml water. The planning of the diets will be in consultation with the participant. There will be at least 1 week between each diet in order to flush out remaining 13C enrichment and to normalize the subjects from the effects of the 4-day diet.

The breath tests will be performed under the supervision of the coordinating investigator. The risks of all described items are considered negligible. There is no direct benefit for the subjects. Due to the fact that we will recruit at the Hanzehogeschool, Wiebengacomplex the chances are that the subjects will be enrolled in a healthcurriculum. Therefore it could be very interesting for the subjects to get a sense of what research entails. Especially dieting, fasting and also the breath test. We offer the subjects the possibility to be present at a final meeting which will take place after the results have been analyzed.

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

- Male

- Age between 18 * 30 years
- Willing and able to adhere to a protein restricted diet for 3 x 4 days
- Be able to fast overnight
- Be able to consume a 500 ml test drink within 5 minutes
- Be able to fast for 5.5 hours
- Body mass index between 20 and 25 kg/m2
- Be able to understand the Dutch language and give written consent

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

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-10-2016
Enrollment:	16
Type:	Actual

Ethics review

Approved WMO

Date:	21-07-2016
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Not approved	
Date:	07-11-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO	
Date:	15-12-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO	
Date:	30-05-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL56982.042.16

Study results

Date completed:	01-09-2017

Actual enrolment: 16