Difference in digestibility of three protein sources between older and younger adults as measured with the dual tracer method

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To determine the difference in amino acid digestibility of milk, sorghum and black beans between older (65-80 years) and younger (20-35 years) adults using the dual tracer method.

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

Summary

ID

NL-OMON51395

Source
ToetsingOnline

Brief title
Protein digestibility in older and younger adults - DiGest study

Condition

- Other condition

Synonym
ageing, senescence

Health condition

veroudering

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: Arla Foods,Dairy Management Inc.,FrieslandCampina B.V.,Nestle,TKI

Intervention

Keyword: ageing, digestibility, protein

Outcome measures

Primary outcome

Blood samples will be drawn every hour until the 5th hour and every 30 minutes afterwards up to 8 hours. Plasma and meal amino acids enrichment will be measured with gas chromatography - isotope ratio mass spectrometry (GC-IRMS) for both isotopes. The ratio between 2H and 13C labelled amino acids in both meal and blood plasma will be determined and amino acid digestibility of the tested protein source will be calculated.

Secondary outcome

- To determine the difference in amino acid digestibility between milk, sorghum and black beans within age groups.

- To explore the difference in blood amino acids kinetics between milk, sorghum and black beans and between older and younger adults.

- To investigate the association between gut health as measured with blood markers and amino acid digestibility of milk, sorghum and black beans.

Study description

Background summary

Older adults should meet their amino acid requirements to prevent development of sarcopenia. Dietary protein quality is of importance, as determined by amino acid composition and digestibility of the consumed protein. There is a need to investigate the impact of ageing on amino acid digestibility and thus quality in vivo. The dual tracer method is an indirect, minimal-invasive method to determine amino acid digestibility in humans. It is expected that amino acid digestibility decreases with age and that the effect between age groups is greater for poorly digestible protein sources.

Study objective

To determine the difference in amino acid digestibility of milk, sorghum and black beans between older (65-80 years) and younger (20-35 years) adults using the dual tracer method.

Study design

A randomised cross-over study design with a dietary protein intervention will be performed. The participants will have three test days, each separated by two weeks. They will consume milk, sorghum and black beans on each test day separately. The order of the protein sources is random.

Intervention

Twenty grams of three deuterium (2H) - labelled protein sources (milk, sorghum and black beans) will be consumed on three different test days. The meals will be divided into 10 portions, consumed every hour. The 2H-labelled protein source is mixed with free 13C-labelled amino acids as reference.

Study burden and risks

Research in older adults is necessary to provide them with suitable nutritional advice. The participants will not benefit directly from participating in this study. Stable isotopes occur in nature, are not radioactive and are not harmful for the subjects. Total blood sample of 450 mL divided over four weeks is not expected to result in any side effects. The burden of this study concerns the obliged consumption of three meals, blood donation and time investment of the screening and three test days.

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

- Age: 20-35 years or 65-80 years
- Body Mass Index (BMI): 20.0 - 30.0 kg/m2
- Veins suitable for blood sampling
- Healthy as assessed with a questionnaire
- Regular and normal Dutch eating habits as assessed with a questionnaire
- Having given written informed consent
- Willing to comply with study procedures
- Accept use of all encoded data, including publication, and the confidential use and storage of all data for 15 years.

Exclusion criteria

- Chronic disease, for example:
o Diabetes mellitus, being treated for high blood glucose or increased fasting blood glucose (> 6.7 mmol/l in finger prick blood)
o Active cardiovascular disease
o Hepatic disease (e.g. hepatitis)

o Renal disease
o Cancer
o Bowel disease (e.g. inflammatory bowel disease, ulcers, bleeding)
o Pancreatitis
- History of medical or surgical events that may affect GI function and the study outcomes, for example:
o Bariatric surgery
o Gastrointestinal tract surgery
o Digestive tract disorder
o Chewing problems
- Medicine use that interferes with GI function and the study outcomes, for example:
o Glucose lowering drugs
o Proton pump inhibitors
o Laxatives
- Habits that interfere with the study outcomes:
o Probiotics and/or protein supplement use
o Smoking
o Drug abuse
o Alcohol consumption for men >21 units/week and >4/day and for women >14 units/week and >3/day
o Following a weight-loss diet, medically prescribed diet or other diet with a low calorie intake or an unbalanced nutrient intake like a vegan or very low carbohydrate diet
o Moderate to high intense physical activity for more than 5 hours a week
o Difficulties with eating breakfast in the morning
- Other:
o Self-reported allergy or intolerance to the tested products (milk, sorghum, black beans)
o Weight loss of more than 3 kg in the month prior to study screening
o Being pregnant or breastfeeding
o For men: Hb <8,5 mmol/l and for women: Hb <7,5 mmol/l
o Recent blood donation (<2 months prior to start of the study) and planning to donate blood (<4 months after the termination of the study)
o Current participation in other research and <2 months previous participation in other research
o Not having a general practitioner
o Not willing to accept information-transfer concerning participation in the study, or information regarding his or her health, like laboratory results and eventual adverse events to and from his general practitioner
o Working at the department of Human Nutrition and Health at Wageningen University & Research

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-11-2022
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	23-05-2022
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL80529.091.22