The incorporation of dietary protein derived amino acids in duodenal epithelium in young and older males.

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To assess the postprandial incorporation of dietary protein derived amino acids in intestinal epithelium in healthy young and older males.

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

Summary

ID

NL-OMON53362

Source
ToetsingOnline

Brief title
GutFeeding study

Condition

- Protein and amino acid metabolism disorders NEC
- Muscle disorders

Synonym
Anabolic resistance, protein malabsorption

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Campina,TKI subsidie Topsector Agri & Food

Intervention

Keyword: Absorption, Digestion, Intestinal mucosa, Proteins

Outcome measures

Primary outcome

1. To assess the postprandial (0-5h) incorporation of dietary protein derived amino acids in duodenal epithelium in healthy young and older males.

2. To investigate whether age affects the postprandial (0-5h) incorporation of dietary protein derived amino acids in duodenal epithelium.

Secondary outcome

1. To assess the postprandial (0-5h) plasma availability of dietary protein derived amino acids in healthy young and older males.

2. To assess postprandial (0-5h) fractional duodenal mucosal and muscle protein synthetic rates in healthy young and older males.

Study description

Background summary

Skeletal muscle tissue is in a constant state of turnover, regulated by the balance between tissue protein synthesis and breakdown rates. Protein ingestion is a major anabolic stimulus for muscle protein synthesis. The anabolic properties of dietary protein largely depend on the protein digestion and amino acid absorption kinetics and subsequent increase in plasma amino acid availability. A substantial part of the ingested protein does not become available in the circulation. This part is either not (yet) digested and absorbed, or the absorbed amino acids are taken up by splanchnic tissues, such as the gut and liver, providing precursors for de novo tissue protein synthesis. It has been suggested that these absorbed amino acids are utilized by intestinal epithelial cells for rapid cell proliferation, generating new cells to maintain healthy mucosa. However, human studies on the incorporation of dietary protein derived amino acids in intestinal epithelium have not been performed. Aging is accompanied by a blunted muscle protein synthetic response

to protein ingestion. This proposed anabolic resistance may be related to a decreased postprandial amino acid release in the circulation, due to greater first-pass splanchnic amino acid extraction in older individuals. Whether dietary protein derived amino acid incorporation in intestinal epithelium is increased with aging remains to be established.

Study objective

To assess the postprandial incorporation of dietary protein derived amino acids in intestinal epithelium in healthy young and older males.

Study design

Cross-sectional, non-therapeutic intervention study design

Intervention

Continuous intravenous stable isotope amino acid tracer infusion will be applied, in combination with oral ingestion of 20g intrinsically labelled milk protein, with plasma, muscle and duodenal mucosa biopsy samples collected at different time points throughout the experimental test day.

Study burden and risks

Participants will come to the laboratory for a total of two visits, comprising of a screening visit (±2h) and one experimental test day (±8h). Two days prior to the test day, participants will have to record their food intake and physical activity performed. During these two days, participants are not allowed to perform heavy physical exercise or drink alcohol. At the experimental test day, they have to arrive in a fasted state.
The stable isotope amino acid tracers that will be infused intravenously are produced according to GMP standards and are safe for human use. Intrinsically labelled milk protein has recently been produced and has been provided by Friesland Campina.
Insertion of catheters in a vein is comparable to normal blood draw and the only risk is a small local hematoma. During the experimental test day, 15 blood samples (150 mL total) will be obtained. The total amount of blood collected during this study is less than half the amount of a blood donation and will be completely restored in approximately one month.
Muscles biopsies will be obtained under local anaesthesia by an experienced physician. The biopsies will be taken through a small (5mm) incision, and will heal completely. The muscle biopsy may cause some minor discomfort comparable to muscle soreness.
Duodenal biopsies will be obtained by an experienced gastroenterologist using gastroduodenoscopy, which is considered a safe routine medical procedure with low risk of complications.

There is no direct benefit for the participants except for their contribution to the scientific knowledge of postprandial protein handling in the human gut to optimize nutrition intervention strategies.

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 sex
- Aged 18-35 years or 67+ years
- Body mass index (BMI) between 18.5 and 30 kg/m2

Exclusion criteria

- History of cardiovascular, respiratory, gastrointestinal, urogenital, neurological, psychiatric, dermatologic, musculoskeletal, metabolic, endocrine, haematological, immunologic disorders, allergy, major surgery and/or laboratory assessments which might limit participation in or completion of the study protocol, interfere with the execution of the experiment, or potential influence the study outcomes (to be decided by the principal investigator and responsible physician)
- Major abdominal surgery interfering with gastrointestinal function (upon judgement of the principal investigator and responsible physician)
- Use of medication which limit participation in or completion of the study protocol, interferes with the execution of the experiment, or potential influences the study outcomes (to be decided by the principal investigator and responsible physician)
- Use of supplementation (i.e. vitamin, pre- and probiotic supplementation) within 14 days prior to testing
- Administration of investigational drugs or participation in any scientific intervention study in the 14 days prior to the study, which may interfere with this study (upon judgement of the principal investigator and responsible physician)
- Specific diet (e.g. vegetarian, vegan, gluten free, no diary) within the study period
- Planning to lose weight during the study period
- Lactose intolerance
- Excessive alcohol consumption (defined as > 14 alcoholic consumptions per week)
- Smoking
- Drug use
- Donated blood two months prior to the test day
- Recent (<1 year) participation in amino acid tracer (L-[ring-2H5]-phenylalanine, L-[ring-2H3]-leucine, L-[ring-2H4]-lysine, L-[ring-2H2]-tyrosine) or intrinsically labelled protein ([1-13C]-phenylalanine, [1-13C]-leucine, [1-13C]-lysine) studies
- No given permission to register participation in electronic patient file at MUMC+ and to add records of gastroduodenoscopy

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	24-07-2023
Enrollment:	16
Type:	Actual

Ethics review

Approved WMO Date:	15-05-2023
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
CCMO	NL83740.068.23