Dietary protein provides building blocks for all human tissues: the metabolic fate of milk protein
an explorative proof-of-principle study

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Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON57138

Source
ToetsingOnline

Brief title
Pro-Organ

Condition

- Other condition

Synonym
Protein metabolism, protein turnover

Health condition

Eiwitmetabolisme

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Fresenius Kabi,FrieslandCampina,TKI;FrieslandCampina;Fresenius Kabi

Intervention

Keyword: Dietary protein, Human, Metabolism, Surgery

Outcome measures

Primary outcome

The main study parameter is the incorporation of dietary protein-derived amino acids in different organ tissues, expressed as % of ingested amount of protein.

Secondary outcome

We expect that in most surgical procedures, muscle tissue will be removed as part of the standard surgical procedure. The second study parameter is the incorporation of dietary protein-derived amino acids in muscle tissue, expressed as % of ingested protein. In case no muscle tissue will be removed as part of the standard surgical procedure, this outcome will not be calculated for that specific participant.

Study description

Background summary

It has been well-established that ~95% of high-quality protein (i.e. milk protein) is digested and absorbed, with the remaining ~5% being excreted in feces. Following absorption, ~10% of dietary protein-derived amino acids are incorporated in skeletal muscle tissue and ~10% is accounted for by protein oxidation. However, the metabolic fate of the remaining ~75% of dietary protein-derived amino acids has not yet been determined. Presumably, these

amino acids are incorporated into other tissues such as the intestine, liver, heart, skin, and brain. However, direct evidence for dietary protein-derived amino acid incorporation is lacking for most tissues. Therefore, the objective of this project is to assess the metabolic fate of ingested dietary protein-derived amino acids. Specifically, we will for the first time quantify the incorporation of dietary protein-derived amino acids in a wide variety of organ tissues in vivo in humans. We hypothesize that dietary protein-derived amino acids are incorporated in all organ tissues, with a relatively larger incorporation in tissues with higher protein turnover rates such as the gut and brain.

Study objective

The main aim of the current study will be to determine the metabolic fate of dietary protein. More specifically, the main aim is to assess the incorporation of protein-derived amino acids in a wide variety of organ tissues in vivo in humans.

Study design

The present study confers to a single-arm prospective study in which all participants receive the same treatment prior to planned surgery that involves (partial) resection of organ tissue.

Intervention

Participants will consume 40 grams of intrinsically L-[1-13C]-phenylalanine labelled milk protein, dissolved in 400 mL water on the evening before planned surgery.

Study burden and risks

The burden and risks associated with participation are small. The nutritional intervention of providing 40 grams of dietary protein before sleep on the evening prior to surgery does not pose any risks. Intrinsically labelled milk protein is physiologically identical to regular milk protein, is considered safe and has been applied extensively within our lab and by others. Collection of tissue samples during planned surgery does not bring any additional risks. Tissue collection will only be performed on organ tissue that will be removed as part of the regular surgical procedure.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

Adults
1. >= 18 years old
2. Planned surgery that involves the (partial) resection of organ tissue
3. 18.5 <= BMI <= 30 kg/m2
4. Written informed consent

Children
1. >= 8 years old and <= 14 years old
2. Planned surgery that involves the (partial) resection of organ tissue
3. 14 <= BMI <= 30 kg/m2
4. Written informed consent by parents

Exclusion criteria

1. Lactose intolerant or allergy to milk proteins
2. Recent (<12 months) participation in L-[1-13C-phenylalanine] tracer studies
3. Cachexia (loss of 5% or more of body weight over the preceding 6 months)
4. Receiving enteral or parenteral nutrition
5. Score of 2 or more on the Malnutrition Universal Screening Tool (MUST)
6. Co-morbidities and neuromuscular disorders of the lower limbs severely interacting with mobility with limited or no opportunity for improvement (e.g. cerebral palsy);
7. Peripheral arterial disease Fontaine III or IV
8. Chronic obstructive pulmonary disease (COPD) GOLD III or IV
9. Use of systemic steroids in the past four weeks, other than indicated for the specific type of surgery
10. Use anti-inflammatory biologicals (e.g. TNF-alfa blockers) in the past four weeks
11. Phenylketonuria (PKU)
12. Surgical intervention in the past four weeks
13. Insulin dependent diabetes mellitus
14. Total parenteral nutrition at day of surgery
15. Pregnancy
16. Neoadjuvant chemo- or radiotherapy in the past four weeks

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2024
Enrollment:	32
Type:	Anticipated

Ethics review

Approved WMO Date:	02-12-2024
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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	NL87518.000.24