# A dual stable isotope method to assess dietary protein quality in humans: Characterization of intrinsically labelled 15N milk protein as a reference protein

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The present project characterizes the use of 15N-intrinsically-labelled milk protein as a reference-protein for development a minimal invasive method that can be used to assess protein quality in human subjects. For this purpose, our primary...

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

## Summary

### ID

NL-OMON43541

**Source**
ToetsingOnline

**Brief title**
stable isotope method to assess dietary protein quality

### Condition

- Other condition

**Synonym**
methodology, non

**Health condition**

geen, methodologie

**Research involving**

Human

## Sponsors and support

**Primary sponsor:** Wageningen Universiteit
**Source(s) of monetary or material Support:** NZO,NZO;Nederlande Zuivel Organisatie

## Intervention

**Keyword:** dietary protein, digestibility, milk protein, stable isotopes

## Outcome measures

### Primary outcome

The ratio of isotopic enrichment (15N/13C) of (total) amino acids of the test

meal and the blood plasma as determined by (gas chromatography*) isotope ratio

mass spectrometry ((GC)-IRMS).

### Secondary outcome

Measurement of total N, urea and ammonia by kinetic UV assay and 15N and 13C

enrichment by GC/IR-MS in urine will be assessed.

# Study description

### Background summary

The evaluation of protein quality has been identified as the top priority question by the Food and Agricultural Organization (FAO) of the United Nations. However, the current available methods do not precisely estimate protein quality, or need invasive procedures. The proposed *dual tracer approach* is a minimal invasive method to evaluate protein quality in humans.

### Study objective

The present project characterizes the use of 15N-intrinsically-labelled milk protein as a reference-protein for development a minimal invasive method that can be used to assess protein quality in human subjects. For this purpose, our primary objectives are to define the digestive and metabolic behaviour and distribution of the 15N-intrinsically-labelled milk protein compared to the

internal standard 13C-spirulina

### Study design

Randomized cross-over trial with two experimental meals.

### Intervention

On two separate test days, subjects will receive a semi liquid meal (pudding) divided in 9 portions, (500 Kcal; meal 1: 27 En% Protein,10 En% fat, 62 En% carbohydrates; meal 2: 14 En% Protein,10 En% fat, 75 En% carbohydrates), made with intrinsically labelled 15N protein powder. Furthermore, the meal will contain a trace amount of 13C-labelled algae protein as an internal standard. Meals will differ in the amount (e.g. 50g or 25g) of 15N-labelled milk protein.

### Study burden and risks

A meal challenge with intrinsically labelled protein and addition of stable isotope tracer is frequently used in postprandial studies. Stable isotopes are naturally occurring isotopes and are not harmful for subjects, as there is no decay. Furthermore, placing venous catheters and blood sampling can occasionally cause a local haematoma or bruise and some participants may report pain or discomfort. Subjects have to come to the research facility three times, a screening visit of 1 hour, and 2 experimental days of 7 hours. Subjects will be financially compensated for participation.

## 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

* Healthy
* Age: 20 * 35 y
* BMI: 18.5 * 25 kg/m2
* Stable dietary habits
* Veins suitable for cannulation (blood sampling)

## Exclusion criteria

* Having a history of medical or surgical events that may significantly affect the study outcome
* Medical drug use accept incidental use of paracetamol
* (Chronic) disease which might influence the study outcomes e.g. diabetes mellitus or any other endocrine disorder, active cardiovascular disease, hepatic disease, renal disease, cancer , bowel disease
* Milk protein or lactose intolerance or allergy
* Alcohol consumption of >14 (women) or > 21 (men) units per week
* Drug abuse
* Moderate intense physical activity (exercise) for more than 5 hours/week
* Reported weight loss or weight gain of > 3 kg in the month prior to pre-study screening
* Reported slimming diet, or medically prescribed diet
* Having a habitual diet with a protein content of <10 En% > 30 En%
* Reported vegan or macrobiotic life-style

# Study design

### Design

| | |
|---|---|
| Study type: | Interventional |
| Intervention model: | Crossover |
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Other |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 09-08-2016 |
| Enrollment: | 10 |
| Type: | Actual |

## Ethics review

Approved WMO

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|---|---|
| Date: | 18-07-2016 |
| Application type: | First submission |
| Review commission: | METC Wageningen Universiteit (Wageningen) |

## 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 |
| --- | --- |
| ClinicalTrials.gov | NCTnotyetassigned |
| CCMO | NL56440.081.16 |