

Metabolic availability of L-lysine from milk powder using indicator amino acid oxidation technique

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20970

Source

Nationaal Trial Register

Brief title

INSPIRE

Health condition

Digestion

Sponsors and support

Primary sponsor: FrieslandCampina

Source(s) of monetary or material Support: FrieslandCampina

Intervention

Outcome measures

Primary outcome

Adults: true metabolic availability of L-lysine in two milk powders compared with a reference crystalline amino acid mixture

Children: relative metabolic availability of L-lysine in two milk powders

Secondary outcome

NA

Study description

Background summary

Protein quality of a food reflects its ability to meet daily tissue amino acid requirements depending on the content, composition and metabolic availability of constituent amino acids. However, to ensure product quality, commercial products are subjected to varying degrees of processing, which leads to loss of bio-availability of proteins due to structural alterations of the amino acids. Therefore, in the present study, our aim is to determine and compare metabolic availability of L-lysine from two differently processed milk powders, among healthy adults (n=7) and children (n=12) using a simple, non-invasive and rapid technique called indicator amino acid oxidation method. The metabolic availability of L-lysine from the milk proteins will be estimated by comparing the indicator oxidation response to varying intakes of L-lysine from milk proteins with the response to varying intakes of synthetic L-lysine using slope ratio method. Similar concept will be applied to determine relative metabolic availability of one milk protein against the reference in the children study. Therefore, the present study will be instrumental in understanding the effect of processing on milk protein bio-availability.

Study objective

Different processing of milk products will have impact on metabolic availability of amino acid

Study design

Adults: 7 study days with one week wash-out in between study days

Children: 5 study days with one week wash-out in between study days

Intervention

Two different milk powders

Contacts

Public

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Scientific

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Eligibility criteria

Inclusion criteria

Adults:

Apparently healthy adult male volunteers

Normal Hb > 13g/l

Age: 20-40 years

Normal BMI between 18.5 to 25 kg/m²

Physical activity level <1.5 assess nu validated questionnaire

Subject to agree to avoid smoking and alcohol consumption for the entire study duration

Subject willing to participate and adhere to the study protocol for 7 consecutive weeks

Children:

Children 6-10 years of age, both sexes

Apparently healthy

BAZ between -2SD and 1 SD

Children and parents willing to participate and adhere to adaptation diets for 5 consecutive weeks

Exclusion criteria

Adults:

History of smoking or taking other leisure drugs in past 3 months and/or study duration

Consumption of alcohol in the previous 24 hr and/or in study duration

History of antibiotics in last month

On iron, protein, multivitamin, and/ or any other supplementation therapy in past 3 months

Unstable weight over last 3 months

Use of medications known to affect intestinal functions and protein metabolism

Participation in any nutritional intervention study in last 3 months

History of food allergy

History of acute illness. gastrointestinal, respiratory tract symptoms of fever in the past 1

week
diagnosed with any acute or chronic medical conditions

Children:

Any acute or chronic illnesses

Menarche

Weight loss in last 1 month

Worm infestation as assessed by stool test

History of antibiotics in last month

On iron, protein, multivitamin, and/ or any other supplementation therapy in past 3 months

Use of medications known to affect intestinal functions and protein metabolism

History of food allergy

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-10-2019
Enrollment:	19
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date: 22-08-2019

Application type:

First submission

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

NTR-new NL7991

Other Mahidol University Central Institutional Reveiw Board : MU-CIRB 2019/109.1906

Study results