Determination of protein digestibility of whey and zein in ileostomates.

Published: 20-02-2018
Last updated: 12-04-2024

This study aims to determine the digestibility of AAs in two protein sources in men and women with normally functioning ileostomies.

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

Summary

ID

NL-OMON46395

Source
ToetsingOnline

Brief title
PROTEOS

Condition

- Other condition

Synonym
none

Health condition

alle, eiwit kwaliteit is van belang voor de juiste keuze voor een eiwitbron in de voeding.

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: global dairy platform,Massey

University;subcontracter of Proteos project of global dairy platform.

Intervention

Keyword: Dietary protein, Digestibility, Ileostomates, Protein quality

Outcome measures

Primary outcome

Ileal AA digestibility of Zein and Whey Protein Isolate.

Secondary outcome

n/a

Study description

Background summary

The evaluation of protein quality has top priority according to Food and Agricultural Organization (FAO) of the United Nations. However, one aspect of protein quality, namely the digestibility of protein is largely unknown. A database on this matter is lacking as it is difficult to measure ileal digestibility in humans.

Study objective

This study aims to determine the digestibility of AAs in two protein sources in men and women with normally functioning ileostomies.

Study design

Intervention study with 6 test days, testing 3 meals each twice.

Intervention

On six separate test days, subjects will receive a meal, consisting of a drink and biscuit. With this, two different protein containing meals, i.e. zein and whey, and a protein-free meal is tested; these three treatments are given at two occasions, thus in total 6 meals are tested. After consumption of the meal, subjects collect their digesta for nine hours.

Study burden and risks

The subject will not benefit from the study except for the contribution to scientific research. Risk associated with intake compounds of the meal is negligible. Subjects have to come to the research facility seven times, a screening visit of 1 hour, and 6 experimental days of 10 hours. Subjects will be financially compensated for participation.

Contacts

Public
Wageningen Universiteit

Stippeneng 4
Wageningen 6708 WE
NL
Scientific
Wageningen Universiteit

Stippeneng 4
Wageningen 6708 WE
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* Male or female
* Age between 18 and 60

* BMI between 18,5 and 27 kg/m2
* Willing to eat animal protein
* Have a well-established and normally functioning terminal ileostomy, with stomal faeces of normal physiological consistency
* Good general health, meaning subjects should be well-recovered from the ileostomy operation, their underlying disease should be cured or in remission and they should not have any other major health problems.

Exclusion criteria

* Taken antibiotics or medication that majorly impair small intestinal digestion and absorption within eight weeks of participating in the study.
* Have been pregnant or breastfeeding in the last 12 months, or plan to become pregnant during the study
* Having renal impairment, coeliac disease or diabetes
* Drug abuse
* Alcohol consumption of >14 units per week
* Having an allergy or intolerance to dairy, corn products or fructose
* Currently taking protein supplements and would not be willing to stop using these during the study
* Being on a controlled diet or dietary weight loss regimen during the two weeks prior to the start of this study and/or during the study
* Personnel of division of Human Nutrition, Wageningen University..
* Current participation in other research from the Division of Human Nutrition
* Not having a general practitioner

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):	04-05-2018
Enrollment:	8
Type:	Actual

Ethics review

Approved WMO Date:	20-02-2018
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
CCMO	NL63446.081.17