Digestibility of Fermotein

Published: 17-03-2021
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The primary objective is to assess the degree of digestibility of 3 different Fermotein products and compare this to a reference commercially available Mycoprotein.

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

Summary

ID

NL-OMON55063

Source
ToetsingOnline

Brief title
MyDi

Condition

- Other condition

Synonym
protein digestion

Health condition

opname van eiwitten

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: The protein brewery

Intervention

Keyword: Amino acid uptake, Digestibility, Mycoprotein

Outcome measures

Primary outcome

The main study parameter is the degree of digestibility determined e.g. the appearance of free amino acids in blood samples collected before and after consumption.

Secondary outcome

Secondary outcomes are plasma glucose and insulin levels.

Study description

Background summary

Mycoprotein is a protein source derived from fungi produced for human consumption. It is high in protein, high in fiber, low in saturated fat and contains no cholesterol. Their functional properties and nutrient content makes them ideal to use as an ingredient for meat alternatives. Fermotein is such a mycoprotein type novel food source. The digestion characteristics of Fermotein are not known, but essential to evaluate their future potential as a sustainable protein source.

Study objective

The primary objective is to assess the degree of digestibility of 3 different Fermotein products and compare this to a reference commercially available Mycoprotein.

Study design

The study has a randomised, cross-over, double blind, controlled design. Four different treatments will be evaluated with a washout period of one week between the test days. On test days, study subjects will receive a product in randomised order. Blood will be collected via a catheter before and up-to five hours after protein consumption.

Intervention

Study subjects will receive a product e.g. Fermotein dry, Fermotein wet, modified Fermotein wet and a reference Mycoprotein. All representing a 20g protein load in, randomised order.

Study burden and risks

This study is not related to a specific group. There are minor risks for the participants of this study. There are no direct benefits for the participants. Fermotein has been analysed thoroughly on safety parameters and no harm is expected. The total amount of blood collected is spread over 5 weeks and we will exclude study participants with anaemia. Blood collection will therefore not expected to cause any problems. Study subjects that will participate in the study will invest approximately 26 hours during the trial.

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 men and women;
* Age between 18 and 70 years ;
* Having veins suitable for blood sampling via a catheter (judged by study nurse/ medical doctor);
* Body mass index (BMI) between 18.5 and 30 kg/m2

Exclusion criteria

* Any metabolic, gastrointestinal, inflammatory or chronic disease (such as diabetes, anaemia,
hepatitis, cardiovascular disease),or having a condition or disease that may lead to an impaired immune system
* History of gastro-intestinal surgery or having (serious) gastro-intestinal complaints;
* History of liver dysfunction (cirrhosis, hepatitis) or liver surgery;
* Kidney dysfunction (self-reported);
* Any use of medication that may suppress the immune system, this will be judged by the medical supervisor;
* Use of medication that may influence the study results, such as gastric acid inhibitors, laxatives, stomach protectors and drugs that can affect intestinal motility, this will be will be judged by the medical supervisor;
* Anaemia (Hb values <7.5mmol/L for women and <8.5mmol/L for men);
* Reported slimming, medically prescribed or other extreme diets or the use of protein supplements;
* Not willing to give up blood donation during the study;
* Current smokers;
* Alcohol intake *4 glasses of alcoholic beverages per day;
* Pregnant, lactating or wishing to become pregnant in the period of the study (self-reported);
* Abuse drugs;
* Having food allergies;
* Not having a general practitioner
* Participation in another clinical trial at the same time;
* Being an employee of the department Food, Health & Consumer Research of Wageningen Food & Biobased Research.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Double blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-04-2021
Enrollment:	12
Type:	Actual

Ethics review

Approved WMO

Date:	17-03-2021
Application type:	First submission
Review commission:	METC NedMec

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
Other	het traject loopt
CCMO	NL74595.081.20