Amino acid profile and post-ingestive consequences of duckweed protein (Lemnae minor) after a single intake with pea protein as reference

Published: 18-09-2017
Last updated: 12-04-2024

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

Summary

ID

NL-OMON44240

Source
ToetsingOnline

Brief title
The Pro-2-study

Condition

- Other condition

Synonym
NVT

Health condition

Verteringskinetiek van eiwit bij gezonde mensen

Research involving

Human

Sponsors and support

Primary sponsor: Stichting Wageningen Research -- Wageningen Food & Biobased Research
Source(s) of monetary or material Support: Wellcome Trust

Intervention

Keyword: amino acid profile, duckweed, plant-based protein, post-prandial effects

Outcome measures

Primary outcome

The main study parameter is the peak value and total amount of amino acids measured in the serum before (t=0 min) and at the various time points after consumption of the two proteins (until t=180 min).

Secondary outcome

Secondary outcomes are the glucose and insulin levels in the blood samples in the same time period of three hours (t=0; t=15, t=30 * t=180) after consumption of the two protein products. Aural temperature, heart rate and blood pressure will be measured before (t=0 min) and after consumption (t=180 min). Finally, subjects will report gastro-intestinal complaints on the test day (consumption of the protein soup) and the subsequent three days via a diary.

Study description

Background summary

The rapid population growth and increasing standards of living are leading to an increasing demand for animal-derived protein. In order to provide sufficient protein to all humans, a transition towards more plant-based diets is required. Duckweed seems an interesting alternative protein source due to its high

protein content and its enormous growth capacity. Duckweed has been used since long as human food in Southeast Asian countries. Animal trials show that fresh and dried duckweed can be fed successfully to various animals (fish, waterfowl, chickens, cattle, sheep and goats) with good results on growth performance when duckweed is part of their habitual diet. Because there is no information available about the postprandial metabolism of duckweed in humans, the Pro-2-study aims to study the amino acid profile and post-ingestive consequences of duckweed protein (Lemnae minor) after a single intake with pea protein as reference.

Study objective

The primary objective is to assess the post-prandial serum amino-acid profile of duckweed protein in healthy adult volunteers in comparison to a another plant-based high-protein crop: green pea. A secondary objective is to assess post-prandial plasma glucose and insulin responses after a single intake of duckweed protein in healthy adult volunteers in comparison with the reference pea protein, as well as the acute health parameters heart rate, blood pressure and aural temperature and the occurrence of gastro-intestinal complaints.

Study design

The Pro-2-study is designed as a randomized, cross-over trial. Subjects will receive the two protein sources in randomized order with a washout period of one week. The proteins will be offered in the form of a green soup with the two products as similar as possible concerning appearance, texture and taste. The study duration is two weeks, as one protein source is given at a time with an interval of one week.

Intervention

Subjects come to the research facility in fasting state. After consuming the soup (~550 ml with 20g of protein), blood samples will be taken each 15 minutes for a period of three hours to assess the free amino acids as well as glucose and insulin levels to get insight into the post-prandial metabolism of the two plant proteins. Heart rate, blood pressure and aural temperature will be measured before consumption (t=0 min) and three hours after consumption (t=180 min). During the test day and the subsequent three days, subjects will report any gastro-intestinal discomfort and potential adverse effects to carefully monitor any inconveniencies during the study.

Study burden and risks

The burden for participants in this study is relatively low. They have to visit the research facility only twice within two weeks. Per test day, eleven blood samples are drawn over a period of 195 minutes, for a total amount of 159 ml

blood, which is 32% of what is taken during blood donation (500ml within 15 minutes). Placing a catheter in a vein in the forearm for blood sampling can be somewhat painful, it may lead to irritation, oedema and in exceptional cases, inflammation may might occur. Participants may experience some level of burden because of the overnight fast and some participants may experience a few gastrointestinal inconveniences due to consumption of the plant-proteins.
The risks of participation are limited. The batch of duckweed that is going to be used for the study, has been analysed thoroughly on several safety parameters. Literature on animal trials with duckweed as feed do not show any negative effects when duckweed is provided as part of their diet and human consumption is common in certain areas of Asia; no reports exist of negative consequences of duckweed consumption in these humans. The dose of duckweed (20 gram protein) provides about 25% of the current daily protein intake and it is a single dose only. So, all together, no adverse effects are expected of this single intake of duckweed. Nevertheless, heart rate, blood pressure and aural temperature as well as potential gastro-intestinal consequences are assessed during the study to carefully monitor any inconveniences. Routinely, AE*s and SAE*s will be registered.
There are no direct benefits for the participants except that they receive information about certain health parameters such as their blood pressure, heart rate, fasting-glucose levels. Furthermore, they contribute to getting insight into the nutritional value of alternative plant proteins. In this way, the participants may contribute to the solution for a relevant societal challenge: sufficient food for everyone in the world.
This study is not group related.

Contacts

Public
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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 as assessed by a health and lifestyle questionnaire and normal blood clinical laboratory tests for haemoglobin, kidney and liver functioning
* Age between 18 and 50 y (boundaries included) at day 01 of the study
* Body mass index (BMI) between 19 and 25 kg/m2 (boundaries included)
* Appropriate veins for blood sampling (judged by a study nurse or medical doctor)
* Willing to abstain from blood donation one month before and during the study
* Willing to abstain from the use of protein supplements during the study period
* Signed informed consent
* Willing to comply with the study procedures

Exclusion criteria

* Any metabolic, gastrointestinal, inflammatory or chronic disease (such as diabetes, anaemia, hepatitis, cardiovascular disease)
* History of gastro-intestinal surgery
* History of liver dysfunction (cirrhosis, hepatitis) or liver surgery
* Kidney dysfynction (eGFR <60 ml/min)
* Any concomitant medication that may influence the study results, such as gastric acid inhibitors or laxatives (occasional use of paracetamol is allowed)
* Intensive sporting activities (>16 hours per week)
* Current smoker
* Alcohol intake *3 glasses of alcoholic beverages per day
* Pregnant or lactating or wishing to become pregnant in the period of the study (self-reported)
* Use of hard drugs
* Known allergies towards the products used in the study
* Not willing to consume chicken bouillon

* Participation in another clinical trial at the same time
* Being an employee of the department of Human Nutrition of Wageningen University or the Consumer Science & Health group of Wageningen Food & Biobased Research

Study design

Design

Study type:	Observational invasive
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2017
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO

Date:	18-09-2017
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
Other	Nederlands trial register; voorlopige nummer 27390. Definitieve identificatienummer komt binnen 4 weken.
CCMO	NL62305.081.17