

# Proteins from duckweed trial

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Objective: The primary objective is to investigate the digestibility of isolated duckweed protein and the isolated benchmark protein whey.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Other condition
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON48747

### Source

ToetsingOnline

### Brief title

ProDuckT-study

### Condition

- Other condition

### Synonym

digestion of proteins

### Health condition

vertering

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Wageningen Universiteit

**Source(s) of monetary or material Support:** Euroese Unie (EFRO)

## Intervention

**Keyword:** digestibility, duckweed, protein

## Outcome measures

### Primary outcome

The primary study parameter is blood amino acids measured before and after consumption of 20 g protein.

### Secondary outcome

The secondary study parameter is blood glucose and insulin measured before and after consumption of 20 g protein.

## Study description

### Background summary

Rationale: The rapid population growth and increasing standards of living are leading to an increasing demand for animal-derived protein. In order to provide sufficient dietary protein for human consumption, a transition towards more plant-based diets is required. Duckweed (*Lemnae minor*) seems an interesting alternative protein source due to its high protein content and its enormous growth capacity. Last two years we conducted two human trials on duckweed to test the digestibility (METC 17/13) and tolerance (METC 18/15) of duckweed plant material. In the Pro-2 study (METC nr 17/13) we observed that plant material is poorly digested and postprandial amino acids were only minimally increased after duckweed consumption. Isolated proteins from duckweed may therefore better qualify as an alternative protein source. Therefore, the study aims to study the digestibility of isolated duckweed protein. The digestibility of the isolated duckweed protein will be compared to an isolated benchmark protein whey.

### Study objective

Objective: The primary objective is to investigate the digestibility of isolated duckweed protein and the isolated benchmark protein whey.

### Study design

Study design: The study is a cross-over, double blind, controlled trial in which study participants will visit the research facility on two occasions under fasting conditions. Subjects will receive two protein sources in randomized order with a washout period of one week. Blood will be collected via a catheter before and up-to 3 hours after protein consumption.

## **Intervention**

Intervention: Study participants will receive 20 grams of isolated duckweed protein and the isolated benchmark protein whey.

## **Study burden and risks**

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: 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. The batch of duckweed that is going to be used for the study, has been analysed thoroughly on several safety parameters and no harm is expected. Also the Pro-2 study and the DIS-study indicated no extra gastro intestinal complaints, even after consumption of a very large dose of plant material (550 gram). The total amount of blood collected during the study is low and therefore not expected to cause any problems. Participants cannot participate if they have anemia. Blood collection via a catheter may cause some discomfort and a bruise. Study subjects that will participate in the study will invest approximately 12 hours during the trial and need to visit the research facility on two occasions.

## **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 50 years
- \* Body mass index (BMI) between 18 and 25 kg/m<sup>2</sup>
- \* Having veins suitable for blood sampling via a catheter (judged by study nurse/ medical doctor)

### **Exclusion criteria**

- \* Any metabolic, gastrointestinal, inflammatory or other chronic disease (such as diabetes, anaemia, hepatitis, cardiovascular disease)
- \* History of gastro-intestinal surgery or having (serious) gastro-intestinal complaints
- \* History of liver dysfunction (cirrhosis, hepatitis) or liver surgery
- \* Kidney dysfunction (self-reported)
- \* Anemia (Hb values <7.5 for women and <8.5 for men)
- \* Use of medication that may influence the study results, such as gastric acid inhibitors, laxatives, stomach protectors and drugs that can affect intestinal motility
- \* Reported slimming, medically prescribed, vegan/vegetarian 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 of drugs
- \* Food allergies for products that we use in the study
- \* Participation in another clinical trial at the same time
- \* Being an employee of the department Consumer Science & Health group 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):	05-03-2019
Enrollment:	12
Type:	Actual

## Ethics review

Approved WMO	
Date:	14-02-2019
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

ClinicalTrials.gov

CCMO

### ID

NCT03823222

NL66859.081.18