Kori-tofu proteins and blood glucose response

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Interventional

Summary

ID

NL-OMON48454

Source
ToetsingOnline

Brief title
KoPro

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
blood glucose, glucose tolerance

Research involving
Human

Sponsors and support

Primary sponsor: Asahimatsu support B.V.
Source(s) of monetary or material Support: Asahimatsu foods

Intervention

Keyword: (Kori-)tofu, glycaemic response, protein

Outcome measures

Primary outcome

The primary study parameter will be the change in blood glucose levels after

consumption of the test meal

Secondary outcome

The secondary study parameter will be the change in blood insulin levels after

consumption of the test meal

Study description

Background summary

There are several types of tofu, an example of a specific type of tofu is called Kori-tofu. Kori-tofu literally means frozen tofu. The production process of Kori-tofu leads to the formation of a higher high molecular weight fraction (HMF) content of the soy proteins. Several clinical studies describe the effects of Kofi-tofu on health. We aim to investigate in participant with an impaired glucose tolerance, whether Kori-tofu protein affects postprandial blood glucose concentrations, when administered as a part of an ordinary high carbohydrate meal.

Study objective

The primary objective is to investigate whether Kori-tofu protein affects postprandial blood glucose concentrations, when administered as a part of an ordinary high carbohydrate meal. The secondary objective is to investigate whether Kori-tofu protein affects postprandial blood insulin concentrations.

Study design

We will test two different test meals: a carbohydrate rich meal with Kofi-tofu (protein) and a carbohydrate rich meal with whey protein as reference. Meals will be matched in macronutrient composition, volume and taste (as much as possible). In order to compare glycaemic responses of both meals, we will

conduct a double-blind, randomised, crossover trial. 24 study participants with an impaired glucose tolerance will visit the research facility on two separate occasions, with a minimum of 1 week between visits. After inserting a cannula, a baseline blood sample will be collected. Participants will thereafter consume one of the test meals. Postprandial blood samples will be collected from the cannula at multiple time points up to 3 hours after consumption of the meal. Study participants will also wear continues glucose meters during the trial.

Intervention

A carbohydrate rich meal with Kofi-tofu (protein) and a carbohydrate rich meal with whey protein as reference (matched with lipid and carbohydrate content).

Study burden and risks

There are minor risks for the participants of this study. There are no direct benefits for the participants. All ingredients are suitable for human consumption and commercially available. The total amount of blood collected during the study (214ml) is not expected to cause any problems. Blood collection via a catheter may cause some discomfort and a bruise. Study subjects that will participate in the study will invest approximately 13 hours during the trial and need to visit the research facility on five 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

Age 50-75yrs
BMI >25 kg/m2
Having veins suitable for blood sampling via a catheter
Having one or more of the following criteria:
o HbA1c> 6%
o fasting glucose >6.1mmol/L
o two-hour glucose levels >7.8 mmol/L on the 75-g oral glucose tolerance test.

Exclusion criteria

* History of gastro-intestinal surgery or having (serious) gastro-intestinal complaints
* History of liver dysfunction (cirrhosis, hepatitis) or liver surgery
* Kidney dysfunction (self-reported)
* Use of medication/supplements that may influence the study results, such as med-icines known to interfere with glucose homeostasis (judged by our study doctor)
* Anaemia (Hb values <7.5 for women and <8.5 for men)
* Reported slimming, medically prescribed or other extreme diets
* Reported weight loss or weight gain of > 5 kg in the month prior to pre-study screening
* Not willing to give up blood donation during the study
* Current smokers
* Alcohol intake *4 glasses of alcoholic beverages per day
* 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 Food, Health & Consumer Research group of Wa-geningen Food & Biobased Research.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-02-2020
Enrollment:	24
Type:	Actual

Ethics review

Approved WMO Date:	26-09-2019
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	ID
Other	het traject loopt
CCMO	NL71213.081.19