Digital Twin

Published: 03-03-2022
Last updated: 05-04-2024

The primary objective of this study is to validate the prediction model on the effect of a standardized mixed meal challenge on postprandial triglyceride levels in a heterogenous group of middle-aged, overweight to obese individuals. The secondary…

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

Summary

ID

NL-OMON51358

Source
ToetsingOnline

Brief title
Digital Twin

Condition

- Other condition
- Lipid metabolism disorders

Synonym
postprandial lipid and glucose metabolism

Health condition

glucosemetabolismestoornissen

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: metabolic responses, postprandial, prediction models

Outcome measures

Primary outcome

The primary study parameter is the postprandial triglyceride responses in blood upon a mixed meal challenge.

Secondary outcome

The secondary study parameters are: postprandial glucose and insulin responses in the blood upon a mixed meal challenge, and extensive phenotyping of the subjects by collecting data on fasting blood profiles of micronutrients, metabolites, and proteins, continuous blood glucose levels (Freestyle Libre), body fat composition (DEXA), liver fat percentage (MRI), habitual dietary intake (FFQ), and physical activity (ActivPAL3).

Study description

Background summary

Elevated triglyceride and glucose levels are major risk factors for cardiovascular diseases. Therefore, mitigating the postprandial increase in triglyceride and glucose levels may help curb a person*s risk of developing cardiovascular diseases. Current strategies to stimulate people to adopt a healthy lifestyle, however, are still insufficient. This is partly due to the fact that nutritional advice is nowadays still given at the population level via general nutrition guidelines, while nutritionist have long been aware that what works for one person may not work for another. Giving personalised dietary advice will help mitigate the postprandial increases in triglyceride and glucose levels, and will assist in the battle against the increase in nutrition-related diseases, such as cardiovascular diseases.

Study objective

The primary objective of this study is to validate the prediction model on the effect of a standardized mixed meal challenge on postprandial triglyceride levels in a heterogenous group of middle-aged, overweight to obese individuals. The secondary objectives are 1) to improve the accuracy of the predicted postprandial TG responses by increasing the number of postprandial TG measurements, 2) to determine which parameters can improve the accuracy of the predicted postprandial TG responses, and 3) to determine if we can also predict the effect of a standardized mixed meal challenge on postprandial glucose levels in a heterogenous group of middle-aged, overweight to obese individuals, and 4) to determine which parameters can improve the accuracy of the predicted postprandial glucose responses.
Another objective is to determine how comparable triglyceride measurements in blood are to measurements in dried blood spots.

Study design

An observational study with three visits, including one mixed meal challenge test day

Study burden and risks

This study is related to a broad general population. There are minor risks for the research subjects of this study. Consumption of the liquid mixed meal may cause some gastro-intestinal discomfort. Blood sampling will be performed via a cannula and the insertion can be a bit painful and may cause a bruise. The amount of blood that is drawn from subjects is within acceptable limits (total amount collected = 186mL). The radiation dose received during the DEXA scan for measuring body composition is negligible compared to the average dose each person in the Netherlands receives per year. Research subjects will invest approximately 13.5 hours in the study. They will visit the Wageningen University research facility three times: once for a short screening, once to collect phenotyping data, and once for a mixed-meal challenge test day. In addition, they will visit Hospital Gelderse Vallei once for an MRI measurement.

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)

Inclusion criteria

- Male or female
- Age 45-75 y
- BMI 25-35 kg/m2
- Suitable veins for insertion of cannula

Exclusion criteria

- Having a gastro-intestinal disease, such as celiac disease, Crohn*s disease, or Ulcerative colitis
- Having a history of intestinal surgery that might interfere with study outcomes, as determined by the medical supervisor. This does not include an appendectomy or cholecystectomy
- Presence of significant systemic diseases, such as diabetes mellitus, cancer, cardiovascular disease or respiratory disease, as determined by the medical supervisor
- Use of medications known to interfere with glucose or lipid homeostasis (e.g. corticosteroids, cholesterol-lowering medication, insulin, metformin), as determined by medical supervisor
- Blood clotting disorders
- Unstable body weight (weight gain or loss >3 kg in the past three months)
- Reported slimming, medically prescribed or other extreme diets
- Alcohol consumption >21 glasses a week
- Anaemia (Hb values <7.5 mmol/L for women and <8.5 mmol/L for men; checked at screening)

- Pregnant, lactating or wishing to become pregnant in the period of the study (self-reported)
- Having a pacemaker, ICD, hearing implant, internal insulin pump, neurostimulator, aneurysm clips placed before 1990, or metal splinter in the eye
- Having claustrophobia
- Not willing to give up blood donation during the study
- Food allergies or intolerances for products that we use in the study
- Unwilling to consume non-vegan test meal
- Recent use of antibiotics (<3 months prior to study start)
- Current smokers
- Abuse of soft and/or hard drugs
- Participation in another clinical trial at the same time
- Being an employee of the Food, Health & Consumer Research group of Wageningen Food & Biobased Research or Human Nutrition and Health Department of Wageningen University

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-03-2022
Enrollment:	38
Type:	Actual

Ethics review

Approved WMO

Date:	03-03-2022
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL79685.091.21
Other	volgt nog