The GLYSIMI study: Elucidating the role of human Small Intestine Microbiota in Interpersonal differences in GLYcemic responses upon consumption of food products. A proof of principle study.

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The objective of this proof-of-concept study is to investigate (differences in) small intestine microbiota and postprandial glycemic responses.

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

Summary

ID

NL-OMON50686

Source
ToetsingOnline

Brief title
GLYSIMI

Condition

- Other condition

Synonym
microbial activity

Health condition

de darm: samenstelling en activiteit microbiota

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: The Global Grants for Gut Health program (GGGH).

Intervention

Keyword: glycemic response, microbiota, small intestine

Outcome measures

Primary outcome

The impact of the (combination of) food product(s) on postprandial glycemic

responses and small intestine microbiota, and whether there is a relation

between differences in small intestine microbiota and glycemic responses.

Secondary outcome

The expression of genes involved in glucose uptake and metabolism in cultured

small intestine epithelial cells after exposure to luminal samples.

Study description

Background summary

Dysregulated glycemic control is a central characteristic of many chronic metabolic diseases. Postprandial glycemic responses are highly variable between subjects consuming the same food product, and may be even opposite between products that contain the same amount of carbohydrates. This variability has been linked to the highly personal fecal microbiome. Glucose is primarily absorbed in the proximal small intestine (SI), but feces however does not represent the SI microbiome. Studies with experimental animals have already shown the importance of the SI microbiota for nutrient digestion and absorption. There is a strong need to confirm this paradigm in humans. We will apply naso-intestinal catheters to sample luminal content from the small

intestine for microbiota analysis after consumption of different food products.

Study objective

The objective of this proof-of-concept study is to investigate (differences in) small intestine microbiota and postprandial glycemic responses.

Study design

A 6 day, proof-of-concept study with crossover design, in which N=20 subjects will participate. Blood glucose levels will be determined by a continuous glucose monitoring device. After a stabilization period, subjects will be equipped with a naso-intestinal catheter, followed by consumption of a standardized (combination of) food product(s). During 4 hrs luminal content and plasma will be sampled. After a wash-out period of 1 day, this procedure will be repeated with a second, different standardized (combination of) food product(s). Breath, urine and fecal samples will also be collected.

Intervention

Consumption of 2 standardized (combination of) food product(s), together with a non-absorbable marker (PEG-4000).

Study burden and risks

Subjects that participate in this study invest approximately 30 hrs. Subjects The subjects may perceive mild discomfort during the placement of the catheter. During the 2 test days, a total volume of 252 mL of blood will be sampled.Participant will be checked for hemoglobin levels to prevent the occurrence of anemia. Regular, commercially available food products will be used as intervention products. Subjects will visit Hospital Gelderse Vallei twice, and will receive ¤425, as reimbursement after completion of the study; they will also receive a repayment of traveling expenditures for each visit.

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

- Males and females
- BMI equal or larger than 25 kg/m2
- Age 40-75 years
- Signed informed consent

Exclusion criteria

- Having a history of medical or surgical events that may either put the subject at risk because of participation in the study, or influence the results of the study, including diabetes type 1, a swallowing disorder, gastrointestinal or liver disease, renal failure, cancer, nose/throat diseases, gastric bypass surgery, use of anticoagulants;
-Having dementia (e.g. Alzheimer's Disease, vascular dementia, Lewy body dementia)
- Having a bleeding/coagulation disorder, including hemophilia, Von Willebrand disease, Bernard-Soulier, Glanzmann thrombasthenia or thrombocytopenia;
- Use of antibiotics within 2 months of starting the study or planned during the study;
- Use of medication that could influence the study results, such as diabetes treatment;
- Use of pro- and prebiotic supplements;
-Sensitive to medical skin adhesives;
-Having an allergy or intolerance towards compounds in the test products;

-Following a vegan diet;
-Excessive alcohol consumption (on average >21 glasses/week for men and >14 glasses/week for women);
-The use of recreational drugs;
-Currently a research subject in another clinical trial;
-Having blood vessels that are too difficult for inserting a cannula/blood drawing;
-Having a hemoglobin level <8.5 mmol/l (men) or <7.5 mmol/l (women);
-Being a blood donor during the duration of the study;
-Not having a General Practitioner (GP);
-Being an employee of Wageningen University, division Human Nutrition and Health.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-12-2021
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	naso-intestinal catheter
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	15-11-2021
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
Other	clinicaltrials.gov
CCMO	NL78737.091.21