Gastric digestion and post-prandial absorption of infant formula differing in protein composition, particularly in whey and casein composition.

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To investigate the effect of whey and casein ratio of IFT on intragastric behavior, gastric emptying and postprandial plasma metabolome

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

Summary

ID

NL-OMON51077

Source
ToetsingOnline

Brief title
Gastric Layering and Monitoring (GLAM II)

Condition

- Other condition

Synonym
nomal digestionphysiology

Health condition

fysiologie

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: Campina,FrieslandCampina

Intervention

Keyword: Gastric emptying, Gastric layering, Infant formula, Post-prandial absorption

Outcome measures

Primary outcome

Top layer volume of the stomach contents

Secondary outcome

Total gastric content volume and blood parameters ((NMR-based) metabolomics

(focusing on the lipid metabolism), plasma free fatty acids, glucose &

insulin).

Study description

Background summary

It is important to develop follow-on and toddler formulae (IFT) that more closely resembles human milk to provide an adequate alternative if mothers do not breastfeed. Results from a previous study suggested that gastric layer formation, which is caused by emulsion instability as a result of gastric acidification/digestion, is different between breastmilk and infant, IFT. This may be due to differences in protein composition, which in turn may contribute to the observed differences in gastric emptying rate between breastmilk and IFT. The hypothesis for the current study is that differences in whey and casein ratio will affect gastric behavior and thereby gastric emptying rate and the postprandial plasma metabolome.

Study objective

To investigate the effect of whey and casein ratio of IFT on intragastric behavior, gastric emptying and postprandial plasma metabolome

Study design

Double-blind cross-over study with two treatments.

Intervention

After an overnight fast, participants will drink 600 mL of one of two IFTs which differ in protein composition. Gastric content will be monitored using Magnetic Resonance Imaging (MRI). MRI scans will be done at baseline and at time points t = 5, 10, 15, 20, 25, 30, 40, 50, 60, 70, 80, 90, 100, 110 and 120 minutes after the start of ingestion and blood samples will be taken at baseline and at t = 15, 30, 45, 60, 75, 90, 105 and 120 minutes for plasma metabolomic analyses. In addition, verbal ratings of hunger, fullness, bloating and nausea will be collected.

Study burden and risks

The risks associated with participation are low, as both phlebotomy and MRI are eminently safe medical techniques. In addition, the IFTs are safe. Each participant will participate in 2 sessions, which require 9 blood withdrawals (in total 120 mL per visit) and multiple MRI scans over a period of approximately 2 hours. These measurements are non-invasive and carry minimal risk. The burden of the sessions is most likely related to mild discomfort as they have to lie still in the MRI for two hours. This will be minimized by the soft mattress on the bed of the MRI, leg rest and a pillow underneath the head. The study is non-therapeutic to the participants.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Male
Age 18 * 45 y
Healthy (self-reported)
Normal-weight (BMI 18.5 * 25kg/m2)
Willing to be informed about incidental findings of pathology
Willing to comply with the study procedures

Exclusion criteria

Allergy or intolerance for cow milk, lactose, soy and/or fish (self-reported)
Gastric disorders or regular gastric complaints, for example heart burn
Use of medication which alters the normal functioning of the stomach, such as:
Medical drug use that influences the GI tract's normal function (e.g. motility, pH, etc.) or the GI tract's microbiota (e.g. antibiotics).
Smoking (>2 cigarettes a week)
Drinking more than 14 glasses of alcohol a week
Having given a blood donation in the past two months
Hb value below 8.4 mmol/L (as measured with finger-prick method)
Having contra-indication to MRI scanning (e.g. having a pacemaker, defibrillator, intraorbital or intraocular metallic fragments, ferromagnetic implants, or being claustrofobic)
Participating in other research during the study period
Not having a general practitioner or unwillingness to share unexpected findings with the general practitioner
Being an employee or student of the division of human nutrition and health

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):	28-01-2022
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	01-11-2021
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
CCMO	NL77717.091.21
Other	Zal parallel worden geregistreerd in Dutch Trial Register

Study results

Date completed:	22-04-2022
Actual enrolment:	20