The difference in postprandial anabolic response between young and elderly, healthy volunteers.

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Our primary objective is to assess the postprandial anabolic response to mixed meal testing in both young and elderly, healthy volunteers. Our secondary objectives are to assess the effect of MMT on glucoregulatory and gut hormones, lipid profiles,...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Hepatic and hepatobiliary disorders
Study type	Observational invasive

Summary

ID

NL-OMON48596

Source
ToetsingOnline

Brief title
TOAST

Condition

- Hepatic and hepatobiliary disorders
- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
postprandial anabolic response

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: NWO

Intervention

Keyword: bile acid signaling, postprandial inflammation, postprandial response, sarcopenia

Outcome measures

Primary outcome

The main study parameters are postprandial bile metabolism expressed as

concentration, area under the curve and inflammatory response as determined by

the whole blood leukocyte counts and plasma cytokines.

Secondary outcome

. To assess the effect of a MMT on:

* Glucoregulatory and gut hormones

* Lipid profiles

* Resting energy expenditure

* Appetite and satiety

* Body composition

* Micriobiome

Study description

Background summary

Rationale: Malnutrition, anorexia and sarcopenia are highly prevalent clinical conditions in the elderly and have a major impact on morbidity and mortality among this subpopulation. The mechanism behind these conditions remains unclear. Research has shown that there is a decreased GLP-1 response in elderly, in comparison with younger subjects. The role of bile acids herein is remains unclear but could be of importance.

In this study, we aim to investigate the difference of postprandial bile acid response to mixed meal testing in young and elderly, healthy volunteers. This study is of importance because it may give us a better understanding of the

anabolic and inflammatory response to mixed meal testing in elderly compared to young healthy volunteers.

The above has been described more extensively in the introduction of our protocol (page numbers: 10+11)

Study objective

Our primary objective is to assess the postprandial anabolic response to mixed meal testing in both young and elderly, healthy volunteers. Our secondary objectives are to assess the effect of MMT on glucoregulatory and gut hormones, lipid profiles, resting energy expenditure, appetite and satiety, body composition and microbiome.

Study design

This study is designed as a single-center, observational study. We will include 9 healthy lean male subjects and 9 healthy elderly subjects. Each subject will undergo 1 mixed meal test.

Study burden and risks

Burden
There will be 2 study visits (1 screening, 1 MMT) in the AMC. The screening visit will take 30 minutes, including physical examination and an overnight fasted venous blood withdrawal (12 ml). The MMT will take approximately 7 hours. During the MMT, subjects will receive a standardized liquid meal consisting of 25% of daily energy expenditure in the form of Nutridrink (Nutricia, Zoetermeer), followed by frequent blood sampling from an intravenous (IV) cannula (total blood withdrawal 120 ml). The total amount of blood withdrawal during the study will be 132 ml. Indirect calorimetry requires that the subjects breathe into a mask for 20 minutes while lying in supine position. Subjects will receive ¤ 65,- for mixed meal test as reimbursement for allocated time and travelling expenses, after completion of the study.

Risks
There is a risk of hematoma and flebitis with the insertion of a intravenous cannula.

Benefit
There is no benefit for the volunteers. This research will provide insight into the anabolic and inflammatory response to mixed meal testing in elderly, which may help us to develop strategies to combat sarcopenia and anorexia in elderly.

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

- Ability to provide informed consent
- 18-30 years or older than 65 years at the time of signing the informed consent
- Body mass index (BMI) 18.5- 25 kg/m2
- Caucasian men
- General good health as determined by medical history, physical examination and blood chemistry by a physician.
- HOMA-IR index: * 2.0 (measured as fasting insulin (pmol/L) x fasting glucose (mmol/L) / 135)

Exclusion criteria

- Major illness in the past 3 months
- Use of any medication
- Gastro-intestinal disease that may influence bile acid signalling metabolism
- History of cholecystectomy or other bile duct abnormalities
- Tobacco smoking
- Drugs abuse
- Alcoholism (>3 units a day)
- Blood chemistry (fasted):
* Creatinine >120 µM
* Glucose * 5.6 mmol/L
* >2 times upper limit reference interval of the following: ASAT, ALAT, GGT, AP
- Strenuous exercise for at least 3 days prior to each study day, defined as more than 1 hour of exercise per day.
- Hypersensitivity to substances in Nutridrink

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-11-2018
Enrollment:	18
Type:	Actual

Ethics review

Approved WMO

Date:	19-10-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL66932.018.18