Exploring the potential of finger prick blood for assessment of BIOmarkers for LOw Grade Inflammation and CVD risk

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The primary objectives of this pilot study are to a-determine whether postprandial LPS and ApoB48 levels can be assessed in finger prick blood of both lean subjects and obese subjects; and b- compare postprandial LPS and ApoB48 levels assessed in…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Lipid metabolism disorders
Study type	Observational invasive

Summary

ID

NL-OMON51003

Source
ToetsingOnline

Brief title
BIOLOGIC

Condition

- Lipid metabolism disorders

Synonym
obesity

Research involving
Human

Sponsors and support

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

Intervention

Keyword: chylomicrons, fat challenge, inflammation, postprandial responses

Outcome measures

Primary outcome

Plasma levels of ApoB48 and LPS in both venous blood samples and finger prick

blood collected under fasting conditions and in response to a high fat

challenge test (1, 2, 4 and 6 hours post ingestion).

Secondary outcome

not applicable

Study description

Background summary

Plasma levels of lipopolysaccharide (LPS) and Apo-B48 may serve as a relevant biomarker of low grade inflammation and risk of cardiovascular diseases (CVD). There are currently no minimally invasive techniques for the measurement of both biomarkers that can be used in samples collected in field settings. In this project we want to explore whether postprandial assessment of biomarkers LPS and ApoB48 in blood withdrawn with a finger prick test can be used as marker for low grade inflammation and risk factor for CVD. Detection via a finger prick would bring a do-it-yourself assay for these markers one step closer when compared to venous punction. This would facilitate monitoring responses to intervention trials targeting dyslipidemia.

Study objective

The primary objectives of this pilot study are to
a-determine whether postprandial LPS and ApoB48 levels can be assessed in finger prick blood of both lean subjects and obese subjects; and
b- compare postprandial LPS and ApoB48 levels assessed in venous blood and finger prick blood within both lean subjects and obese subjects

Study design

This study is an observational pilot study in which postprandial biomarkers of

inflammation and CVD risk will be assessed before and after ingestion of a high fat load.

Study burden and risks

The risks for participation are very small if not negligible. No adverse effects of the high fat challenge were reported previously. Consumption of high amounts of saturated fat may cause some gastro-intestinal discomfort. Blood sampling will be performed via a cannula and the insertion can be a painful and may cause a bruise. Finger prick might also give a short pain sensation and small bruises. The amount of blood that is drawn from participants is relatively small (total amount collected though both cannula and finger pricks = 37.5 ml) and is therefore within acceptable limits. There are no direct benefits for the participants. In the BIOLOGIC study we include both lean metabolic healthy subjects and obese metabolic unhealthy subjects as we expect differences in postprandial responses related to differences in chylomicron production. Therefore it is important to explore these biomarkers in both target groups. This study can therefore be regarded as group-related, non-therapeutic research.

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 18-70 years
* Living in the surroundings of Wageningen (max. 25 km)
* Stable body weight for past 6 months
* Suitable veins for insertion of cannula
-Specifically for lean subjects:
* BMI 18.5-22 kg/m2

-Specifically for obese subjects:
* BMI * 30 kg/m2

Exclusion criteria

* Use of cholesterol-lowering medication
* Use of diabetes medication (e.g. insulin, metformin)
* Use of antibiotics or anti-inflammatory medication
* Known allergy for any of the food components used in the study (milk, cream, sugars)
* Blood clotting disorders
* Current smokers
* Alcohol consumption of > 21 units per week

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):	08-07-2021
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	28-06-2021
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	NL76207.091.20