Assessment and comparison of inflammatory responses upon challenges with glucose, fat, and a combination of glucose and fat

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To assess and compare the inflammatory response upon three acute challenge tests (glucose, fat, glucose + fat) and to compare these responses to a non-challenged condition.

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

Summary

ID

NL-OMON35991

Source
ToetsingOnline

Brief title
Inflammatory responses upon challenges with glucose and/or fat

Condition

- Other condition

Synonym
functioning immune system, inflammatory responses

Health condition

inflammatory responses, algemene gezondheid

Research involving
Human

Sponsors and support

Primary sponsor: TNO
Source(s) of monetary or material Support: Food & Nutrition Delta (innovatieprogramma op initiatief van het Nederlandse bedrijfsleven en kennisinstellingen in dialoog met de ministeries van Economische Zaken;LNV en VWS),Unilever

Intervention

Keyword: Challenge, Fat, Glucose, Inflammation

Outcome measures

Primary outcome

Blood samples will be collected at regular time points during a period of 10 h,

and will be analyzed for inflammatory markers (cytokines/chemokines/acute phase

markers), LPS, oxylipid profile, gene expression, haematology, and serum

clinical chemical profile.

Archive samples will be stored for possible later analyses within the scope of

the study.

Secondary outcome

Body composition (bioimpedance measurement using the InBody); once every

testday

Study description

Background summary

There is currently no consistent data set comparing the effectiveness of different challenge tests on resilience of inflammatory tone (ROIT) in the same study population (e.g. number of biomarkers, effect sizes, pathways etc.). This comparison is needed to select a suitable challenge test for the assessment of dietary impact upon ROIT. The main criteria for a challenge is to induce a (rapid/reproducible/well defined) inflammatory response that mimics the response induced by daily life challenges. The oral glucose tolerance test

(OGTT) is a standardized challenge measuring the glucose/ insulin response. This test is typically used to diagnose diabetes or impaired glucose tolerance. In comparison, an oral lipid tolerance test (OLTT) is not a standardized challenge test, but is typically used to mimic a high fat meal. Both challenges have shown effects on inflammatory markers.

Study objective

To assess and compare the inflammatory response upon three acute challenge tests (glucose, fat, glucose + fat) and to compare these responses to a non-challenged condition.

Study design

This exploratory study is designed as a randomized, open, crossover study with a control condition.

Intervention

Four study substances will be administered once to all participants:
1 = Control (water);
2 = 75 g glucose drink (Oral glucose tolerance test);
3 = 200 ml whipping cream (Oral lipid tolerance test);
4 = 75 g glucose + 200 ml whipping cream (Oral glucose + lipid tolerance test).
The study substances need to be consumed within 10 minutes.

Study burden and risks

Challenges will be administered to a moderately heterogeneous healthy population. It excludes subjects with compromised health and avoids extremes. Participants will stay at the research facility 4 test days of about 12 h. During a period of 10 h, a total of 7 blood samples will be collected per participant using a canula placed into an antecubital vein. The canula will be kept patent by a saline solution infusion. Total amount of blood per test day per participant will be 152.5 ml (total in-study 610 ml). After overnight fasting, a challenge will be administered varying from 300 kcal for the oral glucose tolerance test to 986 kcal for the combined oral glucose + lipid test. The control challenge will consist of water only. Participants are not allowed to eat or drink anything (only water) during the rest of the day. Any discomfort related to administration of the challenges or to not eating or drinking during the test days is temporarily and will subside during the test day. The challenges are not associated with a health risk for the participants.

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

1. Healthy as assessed by:
a. The TNO health and lifestyle questionnaire (P9248 F02)
b. Results of the pre-study laboratory tests in blood
c. Assessment of physical characteristics
2. Age 30-60 y at Day 01 of the study
3. Body Mass Index (BMI) of 20 - 25 kg/m2
4. Voluntary participation
5. Having given written informed consent
6. Willing to comply with the study procedures
7. Willing to give up blood donation during the study
8. Willing to accept use of all nameless data, including publication, and the confidential use and storage of all data for at least 15 years

9. Willing to accept the disclosure of the financial benefit of participation in the study to the authorities concerned.

Exclusion criteria

1. Participation in any clinical trial including blood sampling and/or administration of substances up to 90 days before Day 01 of this study
2. Having a history of medical or surgical events that may significantly affect the study outcome (as judged by the medical investigator)
3. Having a chronic disease related to inflammation or allergy (e.g. rheumatoid arthritis, inflammatory bowel disease, asthma, eczema)
4. Chronic use of medication that may affect inflammatory processes (e.g. NSAIDs, aspirin, antibiotics)
5. Regular use of lipid lowering medication and/or cholesterol lowering products (e.g. Becel Pro-activ)
6. Lactose intolerance or other food allergies
7. Reported slimming or medically prescribed diet
8. Smoking
9. Alcohol consumption > 28 units/week for males and > 21 units/week for females
10.Extreme physical exercise
11. Recent blood donation (<1 month prior to the start of the study)
12. For women: pregnant or lactating or wishing to become pregnant in the period of the study
13. Personnel of TNO (location Zeist), their partner and their first and second degree relatives
14. Not having a general practitioner
15. Not willing to accept notification concerning participation in the study to the subject*s general practitioner
16. Not willing to accept information transfer regarding health aspects, like laboratory results, findings at anamnesis or physical examination and eventual adverse events to and from the subject*s general practitioner

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-06-2011
Enrollment:	14
Type:	Actual

Ethics review

Approved WMO

Date:	20-04-2011
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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	NL36282.028.11