A high-calorie challenge within the healthy range of the population

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Primary:To investigate whether the high calorie challenge test and the predetermined biomarkers could define the healthy ranges of phenotypic flexibility (focusing on the five defined processes) and could indicate the movement towards a less healthy…

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

Summary

ID

NL-OMON38724

Source
ToetsingOnline

Brief title
A high-calorie challenge

Condition

- Other condition
- Glucose metabolism disorders (incl diabetes mellitus)
- Appetite and general nutritional disorders

Synonym
Metabolic diseases, obesity

Health condition

Disorders in metabolic processes

Research involving
Human

Sponsors and support

Primary sponsor: TNO
Source(s) of monetary or material Support: TNO

Intervention

Keyword: High-calorie challenge test, Metabolic health, Nutrition, Phenotypic Flexibility

Outcome measures

Primary outcome

-Markers of glucose metabolism in plasma

-Metabolic related parameters in plasma

-Immunology related parameters in plasma

-Markers of clinical chemistry in serum

-Metabolites measured by metabolomics technology in plasma

-The amount of hunger and satiety measured by the **VASfood** questionnaire.

-Glucose values derived from spectra measured by Raman Spectroscopy.

Secondary outcome

Not applicable

Study description

Background summary

Nutritional science has had difficulty to illustrate specific health-benefit effects related to diet. One of the reasons is that it is difficult to assess changes in health status.
The current clinical study aims to overcome these difficulties by developing a generally accepted standardized test which will be able to demonstrate cause-effect relationships in dietary interventions.
By exposing healthy subjects to a high calorie challenge test, containing generally available ingredients, the adaptive capacities of the most relevant metabolic processes can be quantified and demonstrated.

The main focus during this study will be on the five processes which are most relevant to metabolic health: flexibility of glucose metabolism, lipid metabolism, amino acid metabolism, inflammation and oxidative stress.
The difference in phenotypic flexibility (response of the 5 processes) between the low and high value of each phenotypic characteristic provides insight in the healthy ranges of flexibility, while analyzing the complete range of phenotypic characteristics will provide information on the association/correlation between the range of the phenotypic characteristic and phenotypic flexibility (i.e., the change towards a less healthy situation).
Furthermore, a promising technique of measuring blood glucose levels in a non-invasive manner will be exploratively investigated (Raman spectroscopy).

Study objective

Primary:
To investigate whether the high calorie challenge test and the predetermined biomarkers could define the healthy ranges of phenotypic flexibility (focusing on the five defined processes) and could indicate the movement towards a less healthy situation in an apparently healthy population.

Explorative:
To explore how spectra, measured by Raman spectroscopy, correlate with blood glucose levels that are measured at the same time.

Study design

This is a single centre, explorative, open-label study amongst 100 apparently healthy male and female volunteers (male - female ratio 50:50). All subjects will be equally assigned to 10 groups (of 10 subjects each) based on the three phenotypic characteristics: age, body fat percentage and gender.
Each subject will undergo a high calorie challenge test (duration: app. 8.5 hours), during which they will have to consume a 500 mL high calorie drink within 5 minutes. This drink will be administered in the morning (between 8.00 - 10.00 AM) after an overnight fast.

Intervention

During the study day a dietary challenge test will be applied: a 500 ml drink consisting of a mixture of 75 g glucose, 20 g Protifar (Nutricia), 60 ml palm oil and 320 ml water. This oral challenge drink has to be consumed within 5 minutes.

Study burden and risks

The risks, associated with participation to this study, is minimal. See E9.

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 male / female subjects (ratio: 50-50), 20 to 70 years of age, inclusive. Healthy status is defined by absence of evidence of any active or chronic disease following a detailed medical and surgical history, a complete physical examination including vital signs, hematology and blood chemistry.
2. Body fat percentage within limits of predefined recruitment categories.
3. Able to participate and willing to give written informed consent and to comply with the study restrictions.

Exclusion criteria

1. Participation in an investigational drug or device study within 3 months prior to screening

and / or participation of more than 4 times in the previous year.
2. Loss of blood outside the limits of Sanquin (500 mL) within 3 months prior to screening or not willing to refrain from blood- or plasma donation during the study.
3. Average alcohol consumption > 21 units/week for women and > 28 units/week for men.
4. Change of smoking habits within two months prior to screening.
5. Not having a general practitioner or health insurance.
6. Unacceptable concomitant medication use at baseline, e.g., drugs known or likely to interact with the challenge drink or study assessments
7. Use of dietary supplements less than one month prior to Day 01.
8. Reported slimming or being on a medically prescribed diet.
9. Reported unexplained weight loss or gain of > 2 kg in the last month before screening.
10. Reported food allergy or sensitivity for one of the used ingredients.
11. Females who are pregnant, planning to be pregnant during the study period, or lactating.
12. Not willing to accept information transfer which concerns participation in the study or information regarding health (e.g. laboratory results, findings at health and lifestyle questionnaire, physical examination or eventual adverse events) to and from their general practitioner.
13. Having a systolic blood pressure (SBP) greater than 140 mmHg or diastolic blood pressure (DBP) greater than 90 mmHg (assessed three times at five minutes interval). In the case of isolated systolic hypertension in middle aged volunteers (phenotypic group 5 and 10), the principal investigator will judge whether this condition will cause a clinically significant interference with the study outcome.
14. Clinically significant abnormalities, as judged by the Investigator, in laboratory test results. In the case of uncertain or questionable results, tests performed during screening may be repeated once before determination of eligibility.
15. Inappropriate veins for cannula insertion.
16. Having a chronic disease related to inflammation (such as arthritis).
17. Having a history or symptoms of any significant disease including (but not limited to), neurological, psychiatric, endocrine, cardiovascular, respiratory, gastrointestinal, hepatic, or renal disorder.
18. Any known factor, condition, or disease that might interfere with treatment compliance, study conduct or interpretation of the results such as drug or alcohol dependence or psychiatric disease.
19. Unwillingness or inability to comply with the study protocol for any other reason.;Additional exclusion criteria for the sub-investigation (Raman spectroscopie):
20. Dark skin color according to the Fitzpatrick skin type scale (type 5 or 6).
21. Abnormalities of the skin at the desired measurement location (upper side of forearm).

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-04-2013
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	22-03-2013
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

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	NL43765.056.13