Standardized dietary challenges in healthy and diabetic subjects

Published: 23-08-2012
Last updated: 26-04-2024

To study the adaptive capacity in relevant metabolic processes after a high fat challenge and oral glucose challenge in humans. It is expected that a test method that is generally applicable in clinical food research can be developed.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Interventional

Summary

ID

NL-OMON37022

Source
ToetsingOnline

Brief title
Standardized dietary challenge study

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
diabetes and healthy subjects

Research involving
Human

Sponsors and support

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

Intervention

Keyword: challenge test, type 2 diabetes mellitues

Outcome measures

Primary outcome

glucagon, GLP-1, leptin, insulin, adiponectin, GIP, C-peptide, glutathione

ratio, C reactive protein, SAA, sICAM, sVCAM and metabolites.

Oxygen consumption and carbon dioxide production.

Secondary outcome

free fatty acids, immunological parameters (IL-1b, IL-6, IL-8, IL-18, TNFα,

MCP-1, E-selectin, P-selectin, PAI1, IL1Ra, CXCL9, CXCL10) and others (leptin,

cortisol, , PYY, LPS, CK18, nitrite/nitrate ratio).

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 response to challenge tests may be used to develop biomarkers for the dietary effects on physiological function. The current clinical study aims to investigate whether a high fat challenge test with generally available ingredients can be developed. It is expected that it can quantify the adaptive capacities in the most relevant metabolic processes.

Study objective

To study the adaptive capacity in relevant metabolic processes after a high fat challenge and oral glucose challenge in humans. It is expected that a test method that is generally applicable in clinical food research can be developed.

Study design

This is an explorative randomized cross-over study of 20 healthy males and 20 males with type 2 diabetes mellitus. Both groups will be given the high fat

challenege (OLTT) or the oral glucose tolerance challenge (OGTT) at fasting condition on two different study days. Wash-out between study days will be at least 2 days.

Intervention

Two dietary challenge tests will be applied: an oral lipid tolerance test (OLTT) and an oral glucose tolerance test (OGTT). The OLTT is a drink of about 500 mL which consists of a mixture of 75g glucose syrup, 20g Protifar (Nutricia), 60g palm oil and 64g water. The oral lipid challenge drink should be consumed within 5 minutes.
The OGTT is a drink consisting of 75 g glucose in 300mL water which has to be consumed within 5 minutes.

Study burden and risks

The risks associated with participation to this study are minimal. The medical screening may result in unexpected findings. See E9a.

Contacts

Public
TNO

Utrechtseweg 48
Zeist 3700AJ
NL
Scientific
TNO

Utrechtseweg 48
Zeist 3700AJ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Males, aged 30 to 55 years.
20 healthy volunteers are defined based on 1) Medical history evaluation; 2) Physical examination; 3) results of the prestudy laboratory tests; 4) Body mass index (BMI): 20-25 kg/m2.
20 Type 2 Diabetes, BMI: 25.1-30 kg/m2, willing to stop antidiabetic medication.

Exclusion criteria

1)Uncontrolled bloodpresseure: systolic blood pressure >= 150 mmHg; diastolic blood pressure >= 95mmHg.
2)Use of medication that might interfere with parameters to be measured with one of the challenge tests, with the exception of oral antidiabetic drugs. (use beta blockers, statins, antidiabetic drugs during the study).
3)Smoking
4)physical activity (more than 6 hours per week)
5)unexplained weight loss or gain of > 4 kg in the month prior to the screening
6)followed slimming or medically prescribed diet
7) food allergy or sensitivity
8) For diabetic subjects, fasting glucose < 10mmol/L after stopping metformin for one week.

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):	11-09-2012
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	23-08-2012
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	19-09-2012
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL41396.058.12