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Standardised dietary challenge study

Submission date
21/04/2017

Recruitment status
No longer recruiting

Registration date
25/04/2017

Overall study status
Completed

Last Edited
11/07/2018

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Type 2 diabetes mellitus (T2DM) is a long term condition where a person is unable to control their blood sugar (glucose) levels as they do not produce enough insulin to function properly (insulin deficiency), or that the body's cells don't react to insulin as they should do (insulin resistance). Sugars and fats, two basic nutrients for humans are absorbed into the body in different ways. In people with T2DM there is a disturbance in the absorption of sugar and fat. As more knowledge is available about how people with T2DM respond to fatty and sugary food, there may be a better dietary advice and new products can be developed to treat this disease. The aim of this study is to examine the difference in the absorption of fats and sugars between healthy people and people with T2DM

Who can participate?
20 healthy men and 20 men with T2DM, aged 30 to 70

What does the study involve?
The two groups of participants attend two study days after not eating or drinking anything but water for 10 hours. At the study days, participants are randomly allocated to drink either a high fat drink or a sugary drink. Before drinking the drink and then half an hour, one, two, four, six and eight hours after drinking it, participants have samples of blood taken to assess the way that their bodies are processing the sugar or fats. In addition, half of the participants in each group have samples of breath taken using a special device which are used to measure the amount of oxygen and carbon dioxide present in order to calculate how well they are processing fats and sugars. The remaining participants have a sample of breath or saliva taken which is used to analyse their metabolism.

What are the possible benefits and risks of participating?
There are no notable benefits involved with participating. There is a small risk of pain and bruising when blood samples are collected. In addition, drinking the sugary drinks can sometimes cause nausea, bloating, dizziness and headache. The high-fat drink is safe, it consists of daily used food products, but can also give nausea and bloating.

Where is the study run from?
Centre for Human Drug Research (Netherlands)

When is the study starting and how long is it expected to run for?
July 2012 to January 2013

Who is funding the study?
1. Ministry of Economic Affairs (Netherlands)
2. ABBOTT Nutrition (Netherlands)
3. Friesland Campina (Netherlands)
4. Danisco-DuPont (Netherlands)
5. DSM (Netherlands)
6. Nestlé (Netherlands)

Who is the main contact?
Dr Suzan Wopereis

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
P12.150

Study information

Scientific Title
Standardised dietary challenges in healthy and diabetic subjects

Study objectives

The aim of this study to investigate whether a high fat challenge test with generally available ingredients can be developed, which can quantify the adaptive capacities in the most relevant metabolic processes, and thus applicable for a broad range of functional foods and ingredients targeting these processes in the practice.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Independent Ethics Committee (IEC) of Leiden University Medical Center (LUMC), 17/07/2012, ref: P12.150
Amendments 1-5 were reviewed and approved on 23/08/2012, 19/09/2012, 03/10/2012, 18/10 /2012 and 23/11/2012 respectively.

Study design
Single-centre explorative interventional randomised cross-over study

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet (Dutch only)

Health condition(s) or problem(s) studied
Type 2 Diabetes Mellitus

Interventions
Two groups of participants take part in this study. One group consists of 20 healthy male volunteers and the other group of 20 male subjects with Type 2 Diabetes Mellitus (T2DM). Both groups are given the Fat challenge (OLTT) or the Glucose challenge (OGTT) at fasting condition on two different study days. Wash-out between study days is at least 2 days. One sub-group of 10 subjects from the healthy group underwent a repeated OLTT challenge to assess variability of response in metabolic parameters over time.

On the intervention days, following a 10 hour fast, participants are given a high fat (OLTT) or sugary (OGTT) to drink. A cannula is inserted so that blood can be drawn before (fasting) and at six time-points after consumption of the high-fat or sugary drink (at 0.5, 1, 2, 4, 6 and 8 hours after consumption of the drink). In total, more than 460 mL of blood is collected during examination and research days.

In addition, 10 healthy subjects and 10 subjects with diabetes undergo a QUARK measurement. This involves the head of the person being covered with a transparent plastic cap, which is connected with an extractor fan so that the content and components of their breath can be measured. From the remianing participants, five of each group have samples of breath air collected and five have samples of saliva collected for analysis.

Intervention Type
Other

Primary outcome measure
On study days, at baseline (fasting) and then 0.5, 1, 2, 4, 6 and 8 hours after challenge test, blood samples are collected to measure markers of glucose metabolism (including, but not restricted to, glucagon, GLP-1, leptin, insulin), metabolic related (including, but not restricted to, adiponectin, GIP, C-peptide, glutathione ratio), immunology (including, but not restricted to, C reactive protein, serum amyloid A, soluble intercellular adhesion molecule, soluble vascular cell adhesion molecule) and metabolites measured by metabolomics technology (including, but not restricted to, endogenous metabolites involved in energy metabolism, urea cycle, glucose metabolism, ketonbodies, lipid metabolism and amino acids).

Secondary outcome measures
Gas exchange parameters including oxygen consumption and carbon dioxide production are quantified by the QUARK indirect calorimeter to reflect the energy metabolism in order to establish the metabolic flexibility of subjects when the energy sources are switched between carbohydrate and lipids on the study visits.

Overall study start date
17/07/2012

Completion date
09/01/2013

Eligibility

Key inclusion criteria
All participants:
1. Men, aged 30 to 70 years, inclusive, on study day 1
2. Regular Dutch eating habits (3 main meals including bread) as assessed by the health and lifestyle questionnaire
3. Subject needs to be in a healthy condition or diagnosed as T2DM as assessed by
3.1. Medical history evaluation
3.2. Physical examination
3.3. Results of the pre-study blood test of biochemistry and HbA1c
4. Able to participate in the study, willing to give written informed consent and to comply with the study procedures and restrictions including no use of food supplements
5. Appropriate veins for cannula insertion

Healthy volunteers:
Body mass index (BMI): 20.0-25.0 kg/m2

Patients
1. Diagnosed as T2DM evidenced by a documented history and use of prescription oral glucose-

lowering drug(s)
2. Body mass index (BMI): 25.1-34.9 kg/m2

Participant type(s)
Mixed

Age group
Adult

Sex
Male

Target number of participants
40 (20 healthy men and 20 diabetes type 2 men)

Key exclusion criteria
All participants:
1. Participation in any clinical trial including blood sampling and/or administration of substances up to 90 days before Day 1 of this study
2. Participation in any non-invasive clinical trial up to 30 days before Day 01 of this study, including no blood sampling and/or oral, intravenous, inhalatory administration of substances
3. Uncontrolled hypertension: systolic blood pressure ≥ 150 mmHg; diastolic blood pressure ≥ 95 mmHg.
4. Having a history of medical or surgical events other than T2DM that may significantly affect the study outcome, including any inflammatory diseases (e.g. arthritis), psychiatric history, or any gastro-intestinal disorder.
5. Use of medication that might interfere with parameters to be measured or with one of the challenge tests
6. For diabetic subjects, fasting glucose < 7mmol/L after stopping oral antidiabetic treatment for 3 weeks
7. For diabetic subjects: use of insulin
8. Smokers
9. Active in competitive sports, active in recreational sports for more than 6 hours/week, physical activity considered by the screening physician to be too intense because it may jeopardize the study objectives (this includes but is not limited to unusual exercise, intermittent training programs, unusual manual labor, etc)
10. Reported unexplained weight loss or gain of > 4 kg in the month prior to the pre-study screening
11. Reported slimming or medically prescribed diet
12. A reported food allergy or sensitivity
13. Not having a general practitioner
14. Not willing to accept information transfer which concerns participation in the study, or information regarding health, like laboratory results, findings at anamnesis or physical examination and eventual adverse events to and from his general practitioner.
15. Not willing to give permission to have the general practitioner to be notified upon participation in this study.

Date of first enrolment
24/08/2012

Date of final enrolment

10/12/2012

Locations

Countries of recruitment
Netherlands

Study participating centre
Centre for Human Drug Research
Zernikedreef 10
Leiden
Netherlands
2333 CL

Sponsor information

Organisation
TNO

Sponsor details
Utrechtseweg 48
Zeist
Netherlands
3704 HE

Sponsor type
Research organisation

Website
www.tno.nl

ROR
https://ror.org/01bnjb948

Funder(s)

Funder type
Government

Funder Name
Ministerie van Economische Zaken

Alternative Name(s)
Ministry of Economic Affairs, Netherlands Ministry of Economic Affairs, EZ

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Netherlands

Funder Name
ABBOTT Nutrition

Funder Name
Friesland Campina

Funder Name
Danisco-DuPont

Funder Name
DSM

Funder Name
Nestlé

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date
31/12/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	29/08/2017		Yes	No