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Diabetes and plant food products

Submission date
21/09/2012

Recruitment status
No longer recruiting

Registration date
03/10/2012

Overall study status
Completed

Last Edited
18/04/2017

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
The most common form of diabetes, type 2 diabetes mellitus (T2DM), is a growing health problem worldwide. T2DM is linked to a number of severe complications, as well as increasing the risk of heart disease (cardiovascular disease) and cancer. There is a great deal of evidence to suggest that these diseases are caused by too much sugar in the blood (hyperglycaemia), which leads to an increase of free radicals causing irreversible damage to cells (oxidative stress). Studies have shown that a healthy diet can help to prevent oxidative stress as it is rich in vitamins and minerals that are important for repairing and protecting the cells in the body. Additionally, there is evidence that replacing saturated fatty acids (SFA) in the diet with polyunsaturated fatty acids (PUFA) such as omera-3 can also help to protect the body and prevent diseases. This study aims to investigate the potential of a vegetable and PUFA rich diet to reduce levels of oxidative stress, and to see whether the results of this will be the same in diabetic and non-diabetic people.

Who can participate?
Adults with insulin treated (ITDM2) or non-insulin dependent (NIDDM) type 2 diabetes, and healthy age-matched controls.

What does the study involve?
All participants (both diabetics and non-diabetics) are randomly assigned into one of two groups. The first group (control group) are provided with information about the benefits of a healthy diet, specifically about the importance of fat quality and the role of vegetables in a balanced diet. The second group (intervention group) are provided with the same information, but are also given 300g vegetables and 25ml of plant oil, as a replacement for saturated fats, to eat every day for 8 weeks. Blood samples are taken before the intervention starts, after 4 weeks (half way through the intervention), after 8 days (the end of the intervention period), and after 16 weeks (8 weeks after the end of the intervention period).

What are the possible benefits and risks of participating?
There are no specific benefits of participating aside from the potential health benefits of eating more vegetables and reducing saturated fat in the diet. There are no risks, except for the possibility of digestive discomfort because of the change to the diet.

Where is the study run from?
University of Vienna (Austria)

When is the study starting and how long is it expected to run for?
January 2009 to December 2012

Who is funding the study?
1. European Union through the cross-border cooperation programme (Slovakia - Austria)
2. Austrian Ministry of Health (Austria)

Who is the main contact?
Professor Karl-Heinz Wagner

Contact information

Type(s)
Scientific

Contact name
Prof Karl-Heinz Wagner

Contact details
University of Vienna
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Effect of natural food products on complications in diabetes mellitus type 2

Acronym
DIAPLANT

Study objectives
A diet rich in vegetables and a polyunsaturated fatty acids (PUFA) rich plant oil improves DNA stability in type 2 diabetic subjects.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Committee of the City of Vienna, 16/11/2009, ref: EK09-218-VK_NZ

Study design
Randomized prospective randomised controlled trial.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Type 2 diabetes and complications of Type 2 Diabetes mainly cardiovascular disease

Interventions
All participants (diabetics and non-diabetics) receive information about the beneficial effects of a healthy diet with special focus on the importance of fat quality and the role of vegetables in a balanced diet. Participants are randomly assigned to the intervention or information only group.

Subjects of the information only group received only the above mentioned information, while subjects of the intervention group received additionally 300 g of vegetables and 25 ml of plant oil per day. The participants are instructed to use the plant oil as replacement for saturated fatty acids (SFA). A reference cup and a booklet with recipes, instructions for replacement of SFA and usage of the plant oil (oil is not allowed to be heated up, but added to warm foods) is provided to the participants. A variety of frozen vegetables is given to subjects every 2 weeks. Participants can choose the order of consumption of the provided vegetables. A dietary diary has to be completed, and fatty acid profile, γ-tocopherol and carotenoid concentrations in plasma are measured to monitor compliance.

The intervention period lasts 8 weeks, followed by a period of 8 weeks in which no intervention food is provided. Blood samples are taken before the intervention, after 4, 8 (end of intervention period) and 16 weeks.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. DNA damage (single and double strand breaks): Comet assay in peripheral blood mononucleated cells (PBMCs), performed at baseline, after 4, 8 (end of intervention) and 16 weeks
2. Chromosomal damage: Cytokinesis-block micronucleus assay in PBMCs and buccal cells, performed at baseline and after 8 weeks

Secondary outcome measures
1. Lipid metabolism: total cholesterol, high density lipoprotein (HDL), low density lipoprotein (LDL), triglycerides (enzymatically, Aeroset, Abbott Diagnostics), LDL-subfractions (Lipoprint LDL system) performed at baseline, after 4, 8 (end of intervention) and 16 weeks, except for LDL subfractions, which were measured at baseline and after 4 and 8 weeks
2. Glucose metabolism: fasting plasma glucose (enzymatically by the hexokinase method; Aeroset, Abbott Diagnostics), glycosylated haemoglobin (automated Glycohemoglobin Analyzer), performed at baseline, after 4, 8 (end of intervention) and 16 weeks
3. Inflammation: IL-6 (Elisa), C-reactive protein (CRP) (hs-Elisa), performed at baseline, after 4 and 8 weeks
4. Metabolomics: LCMS-based analysis, performed at baseline and after 8 weeks

Overall study start date
01/01/2009

Completion date
31/12/2012

Eligibility

Key inclusion criteria
1. Stable metabolic control (constant medication regarding glucose, lipid and uric acid metabolism)
2. Glycated haemoglobin (HbA1c) concentration <9.5%
3. Serum total cholesterol (TC) <300 mg/dl (<7.76 mmol/l)
4. Serum triglycerides (TG) <500 mg/dl (<5.7 mmol/l)
5. Serum creatinine <2.5 mg/dl (<221 µmol/l)
6. Stable body weight, constant dietary habits and physical activity levels for at least four weeks before entry to the study

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants

100

Key exclusion criteria
1. Change of dietary habits
2. Frequency of physical activity or body weight within the study period
3. Smoking
4. Intake of fish oil capsules and other fatty acid supplements
5. Change of medication

Date of first enrolment
01/01/2009

Date of final enrolment
31/12/2012

Locations

Countries of recruitment
Austria

Study participating centre
University of Vienna
Vienna
Austria
1090

Sponsor information

Organisation
European Regional Development Fund (EFRE) (Austria)

Sponsor details
Schlesingerplatz 2
Vienna
Austria
1080

Sponsor type
Government

Website
http://www.sk-at.eu

Funder(s)

Funder type
Government

Funder Name
European Union (EU), through the cross-border cooperation programme Slovakia Austria 2007-2013 (http://www.sk-at.eu) ref: N00039

Funder Name
Austrian Ministry of Health (Austria)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results:	01/03/2013		Yes	No
Results article	Results:	01/01/2014		Yes	No