

# Diabetes and plant food products

<b>Submission date</b> 21/09/2012	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 03/10/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 18/04/2017	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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 omega-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  
Althanstrasse 14  
Vienna  
Austria  
1090

## Additional identifiers

## 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

## Study type(s)

Treatment

## 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,  $\gamma$ -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(s)

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

## Key secondary outcome(s)

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

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**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)

## 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

**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?
<a href="#">Results article</a>	Results:	01/03/2013		Yes	No
<a href="#">Results article</a>	Results:	01/01/2014		Yes	No