

The effect of dietary rapeseed (canola) versus olive oil supplementation on serum lipids, liver enzymes and postprandial inflammatory responses in adipose tissue in obese men.

Submission date 23/09/2014	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 08/10/2014	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 08/10/2014	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

This study investigates the benefits of nutritional unsaturated fats on blood lipids (the fat in your blood) and metabolism in fat tissue (the process of breaking down fat for energy) for people who are overweight. Rapeseed (canola) oil and olive oil are both recommended for a healthy diet because of their high content of unsaturated fats. However, these oils contain different types of unsaturated fats. Here, we want to compare the two and then improve the nutritional recommendations for overweight people.

Who can participate?

Overweight men aged 18-65.

What does the study involve?

Participants are randomly allocated into one of two groups. Those in group 1 are given 50 g of rapeseed (canola) oil to add to their daily food for 4 weeks. Those in group 2 are given 50 g of olive oil to add to their daily food for 4 weeks. At the end of the fourth week early in the morning blood is taken for analysis of lipid levels. Also, we will use a thin needle to take a sample of about 1 gram of fat from under the skin near the belly button under a local anaesthetic. Then participants are given a meal. Blood and a second sample of fat are taken again after four hours of the meal. The samples of fat are then analysed in the laboratory.

What are the possible benefits and risks of participating?

Participants will get information on their blood lipid levels and how overweight they are. Taking a sample of fat may result in a bruise, a small scar or an infection. In the case of developing a bruise, it will disappear completely within weeks. In the case of developing a scar, it will be almost invisible (smaller than 3 millimetres). It is very unlikely that an infection will develop, since this procedure will be performed under sterile conditions.

Where is the study run from?

German Institute of Human Nutrition Potsdam Rehbruecke (Germany).

When is the study starting and how long is it expected to run for?

September 2010 to October 2011.

Who is funding the study?

The Union for the Promotion of Oil and Protein Plants e.V. (Union zur Foerderung von Oel- und Proteinpflanzen e.V) (Germany)

Who is the main contact?

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Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

N/A

Study information

Scientific Title

Single centre, randomized study to investigate the effect of dietary rapeseed (canola) versus olive oil supplementation on serum lipids, liver enzymes and postprandial inflammatory responses in adipose tissue in obese, but otherwise healthy men.

Acronym

Rapeseed and olive oil study

Study objectives

Rapeseed and olive oil are both known as favourable nutritional components. Both oils contain a high and almost equal amount of MUFA, whereas rapeseed oil contains more PUFA, especially

ALA and n-6 linoleic acid. This study aimed to investigate whether a daily supplementation with 50 g of rapeseed oil has beneficial effects on serum lipids, liver enzymes and inflammation compared to a daily supplementation with 50 g of olive oil.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The ethical committee of the University of Potsdam, Germany, 03/11/2010, ref: 1/2010, 5/29

Study design

Single-centre randomized 4-week dietary intervention study of two arms (rapeseed vs olive oil)

Primary study design

Interventional

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Obesity

Interventions

Eligible individuals were randomized into two treatments to receive a four week daily supplementation with either 50 g of rapeseed oil or 50 g of olive oil. At the end of the supplementation individuals underwent a biopsy of subcutaneous adipose tissue at fasted conditions at 08:30 am, followed by a test meal of 835 kcal and an additional biopsy of subcutaneous adipose tissue four hours after the test meal.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

To assess the influence of a daily nutritional supplementation with either 50 g of rapeseed oil or 50 g of olive oil to an isocaloric diet on body composition, serum lipids, serum liver enzymes and inflammatory gene expression in sub cutaneous adipose tissue. Body composition will be determined using an air-displacement plethysmography system and serum lipids and liver enzymes will be measured using standard techniques in a certified laboratory at the German Institute of Human Nutrition before and four weeks after dietary intervention. Inflammatory gene expression in sub cutaneous adipose tissue will be measured four weeks after dietary intervention using quantitative real time-PCR.

Key secondary outcome(s)

To assess the influence of a daily nutritional supplementation with either 50 g of rapeseed oil or 50 g of olive oil to an isocaloric diet on plasma n-6 and n-3 PUFA content and plasma n-6/n-3 ratio before and four weeks after dietary intervention. n-6 and n-3 PUFA content will be determined after lipid extraction from plasma using thin layer chromatography and gas chromatography. The plasma n-6/n-3 ratio will be calculated.

Completion date

31/10/2011

Eligibility

Key inclusion criteria

1. Males, age between 18 and 65 years
2. Obesity, BMI between 27-35 kg/m²

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Male

Key exclusion criteria

1. Diabetes mellitus
2. Alcohol or drug abuse
3. Any medical treatment that affects glucose metabolism, treatment with corticosteroids, treatment with monoaminooxidase inhibitors
4. Any treatment with anticoagulants or any known diseases that affect blood clotting

Date of first enrolment

01/09/2010

Date of final enrolment

31/10/2011

Locations

Countries of recruitment

Germany

Study participating centre

Arthurt-Scheunert-Allee 114-116

Nuthetal

Germany

14558

Sponsor information

Organisation

The Union for the Promotion of Oil and Protein Plants e.V. (Union zur Foerderung von Oel- und Proteinpflanzen e.V) (Germany)

ROR

<https://ror.org/041n30849>

Funder(s)

Funder type

Research organisation

Funder Name

The Union for the Promotion of Oil and Protein Plants e.V. (Germany)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration