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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

Registration date
08/10/2014

Overall study status
Completed

Last Edited
08/10/2014

Condition category
Nutritional, Metabolic, Endocrine

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 benefical 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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet
Not available in web format. Please use the contact information below to request Information material.

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 measure

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.

Secondary outcome measures
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.

Overall study start date
01/09/2010

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

Age group
Adult

Lower age limit
18 Years

Sex
Male

Target number of participants
20 randomised individuals

Key exclusion criteria
1. Diabetes mellituis
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
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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)

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Research organisation

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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

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