

Study of the bioavailability of triterpenoids from pomace oil and their role on processes involved in the formation of the atherosclerotic plaque

Submission date

08/10/2010

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

16/06/2011

Overall study status

Completed

☐ Statistical analysis plan

☐ Results

Last Edited

16/06/2011

Condition category

Nutritional, Metabolic, Endocrine

☐ Individual participant data

☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

AGL2008-02285/ALI

Study information

Scientific Title

A double-blind, randomised controlled trial to assess the bioavailability of triterpenoids from pomace oil and their role on processes involved in the formation of the atherosclerotic plaque

Acronym

BIOTERPENOS

Study objectives

Oleanolic acid, a bioactive component of pomace olive oil is bioavailable in relation to its protective effect on processes involved in the beginning and progression of the atherosclerotic plaque

Ethics approval required

Old ethics approval format

Ethics approval(s)

The ethics committee (Comisión de Bioética [CSIC]), 4th of August 2008, ref: AGL2008-02285

Primary study design

Interventional

Study design

Postprandial double blind interventional study

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Atherosclerosis

Interventions

1. Administration of meals in fasting conditions
2. Each meal will provide the same nutrient composition but the fat source will change
3. Three different fat sources will be compared:
 - 3.1. Virgin olive oil
 - 3.2. Pomace olive oil
 - 3.3. Pomace olive oil enriched in oleanolic acid up to 600 ppm
4. Each subject consumes a test meal consisting of brown bread (71g) spread with 50g of one of the three oils followed by a skimmed yoghurt (125g), with a 1 week wash-out period between each test meal
5. The subjects are asked to refrain from consuming alcohol or smoking 24h before each experiment
6. Blood samples are taken 2 and 4h postprandially
7. During this time the subjects are allowed to drink water and/or decaffeinated coffee ad libitum

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

1. Postprandial lipid composition of triglyceride-rich lipoproteins
2. Presence and concentration of oleanolic acid in serum and triglyceride-rich lipoproteins

Key secondary outcome(s)

1. Foam cell formation from macrophages (THP-1 cell line) after treatment with postprandial triglyceride-rich lipoproteins
2. Release of inflammation markers by macrophages (THP-1 cell line) after treatment with postprandial triglyceride-rich lipoproteins
3. Receptor expression in macrophages (THP-1 cell line) after treatment with postprandial triglyceride-rich lipoproteins

Completion date

31/12/2011

Eligibility**Key inclusion criteria**

Healthy males not suffering from hypertriglyceridemia

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Male

Key exclusion criteria

1. Age lower than 18 years and higher than 55 years
2. Hypertriglyceridemia
3. Hypertension
4. Coronary heart disease (CHD)
5. Renal or hepatic disease
6. Obesity
7. Diabetes
8. Alcoholism
9. Smoking
10. Under pharmacological treatment affecting lipid metabolism, coagulation or any condition of the study

Date of first enrolment

01/01/2009

Date of final enrolment

31/12/2011

Locations

Countries of recruitment

Spain

Study participating centre

Instituto de la Grasa (CSIC)

Seville

Spain

41012

Sponsor information

Organisation

Spanish Ministry of Science and Innovation (Ministerio de Ciencia e Innovación [MICINN]) (Spain)

Funder(s)

Funder type

Government

Funder Name

Spanish Ministry of Science and Innovation (Ministerio de Ciencia e Innovación [MICINN]) (Spain)

- Plan Nacional de I+D+I (ref: AGL2008-02285/ALI)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration