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

Submission date	Recruitment status	[ ] Prospectively registered
08/10/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
16/06/2011	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
16/06/2011	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
AGL2008-02285/ALI

Study information

Scientific Title
A double-blind, randomised controlled trial to assess the bioavilability of triterpenoids from pomace oil and their role on processes involved in the formation of the atheroclerotic 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

Study design
Postprandial double blind interventional study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

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

Health condition(s) or problem(s) studied
Atherosclerosis

Interventions
1. Administration of meals in fasting conditions
2. Each meal will provide the same nutrient compositon 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 consume a test meal of 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 asre 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 measure
1. Postprandial lipid composition of triglyceride-rich lipoproteins
2. Presence and concentration of oleanolic acid in serum and triglyceride-rich lipoproteins

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

Overall study start date
01/01/2009

Completion date
31/12/2011

Eligibility

Key inclusion criteria
Healthy males not suffering from hypertriglyceridemia

Participant type(s)
Patient

Age group
Adult

Sex
Male

Target number of participants
12

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
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Sponsor information

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

Sponsor details
Deputy General of Research Projects
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Sponsor type
Government

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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

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