

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

<b>Submission date</b> 08/10/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 16/06/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 16/06/2011	<b>Condition category</b> 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

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Prof Valentina Ruiz-Gutierrez

### Contact details

Instituto de la Grasa (CSIC)

Av. Padre García Tejero, 4

Seville

Spain

41012

+34 (0)95 4611550

valruiz@ig.csic.es

## 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 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

## 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 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 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 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

**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

Spain

41012

**Sponsor information****Organisation**

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

**Sponsor details**

Deputy General of Research Projects

(Subdirección General de Proyectos de Investigación)

Albacete, 5

Madrid

Spain

28027

+34 (0)91 6037743

informa@micinn.es

**Sponsor type**

Government

**Website**

<http://www.micinn.es/>

## **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