

# Molecular mechanisms involved in the protective role of olive oil in the development of atherosclerotic processes

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 28/07/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 17/08/2010	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
PI04/1308

## Study information

**Scientific Title**

Molecular mechanisms involved in the protective role of olive oil in the development of atherosclerotic processes: a parallel randomised controlled double-blind clinical trial with three arms of dietary intervention

### **Study objectives**

A traditional Mediterranean diet will modulate the expression of protective genes related with atherosclerosis processes. Virgin olive oil rich in phenolic compounds will provide further benefits.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

The local medical ethics committee (Comitè Ètic d'Investigació Clínica de l'Institut Municipal d'Assistència Sanitària [CEIC-IMAS]) approved on the 13th September 2004 (ref: 2004/1827/I)

### **Study design**

Parallel randomised controlled double-blind clinical trial

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Cardiovascular risk

### **Interventions**

Volunteers were grouped randomly into three groups (n = 30 each one) to receive during 3 months the following treatments:

1. Traditional Mediterranean diet with virgin olive oil (TMD+VOO)
2. Traditional Mediterranean diet with washed virgin olive oil (TMD+WOO)
3. Habitual diet

For obtaining the washed virgin olive oil, the virgin olive used for the Group 1 treatment was washed by a procedure developed in the Instituto de la Grasa, Sevilla, Spain. This washed virgin olive oil maintained the same characteristics as group 1's virgin olive oil with the exception of the phenolic content which was not present. Olive oils were provided to the subjects of both groups 1 and 2 in sufficient amount for the entire family (15 L/per volunteer) during the intervention period of for cooking and raw purposes. Volunteers were assessed by the nutritionist to maintain their habitual lifestyle (i.e, physical activity, etc). Volunteers of groups 1 and 2 received intensive nutritional advice by trained nutritionists concerning the traditional Mediterranean diet pattern. At the end of the intervention, volunteers compliance was evaluated by values of tyrosol and hydroxytyrosol, the major virgin olive oil phenolic compounds in their first morning spot urine samples.

### **Intervention Type**

Drug

### **Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

Olive oil (with/without phenolic content)

**Primary outcome(s)**

Gene expression changes related to cardiovascular risk, measured at baseline and after 3 months of intervention. Blood samples were collected from 8.00 to 10.00 a.m. at fasting state. Spot morning urine samples were collected.

**Key secondary outcome(s)**

Oxidative stress and Inflammation, measured at baseline and after 3 months of intervention. Blood samples were collected from 8.00 to 10.00 a.m. at fasting state. Spot morning urine samples were collected.

**Completion date**

20/10/2008

**Eligibility**

**Key inclusion criteria**

Healthy volunteers aged 20 - 50 years old, either sex

**Participant type(s)**

Healthy volunteer

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Key exclusion criteria**

1. Intake of antioxidant supplements
2. Intake of acetosalicylic acid
3. Intake of any other drug with established antioxidative properties
4. Athletes with high physical activity (greater than 3000 kcal per week in leisure-time physical activity)
5. Obesity (body mass index [BMI] greater than 30 kg/m<sup>2</sup>)
6. Hypercholestromaemia greater than 8.0 mmol per litre or dyslipidaemia therapy indication
7. Diabetes
8. Hypertension (systolic blood pressure [SBP] greater than 140 mmHg, diastolic blood pressure [DBP] greater than 90 mmHg)
9. Multiple allergies
10. Coeliac or other intestinal diseases
11. Any condition that limits the mobility of the subject making study visits impossible
12. Life-threatening illnesses such as cancer or a severe disease with a less than 3-year

expectancy

13. Other diseases or conditions that could worsen adherence to the measurements or treatments

14. Vegetarians and people following special diets

15. Alcoholism or other drug addiction

**Date of first enrolment**

20/10/2007

**Date of final enrolment**

20/10/2008

## **Locations**

**Countries of recruitment**

Spain

**Study participating centre**

**PRBB**

Barcelona

Spain

08003

## **Sponsor information**

**Organisation**

Spanish Olive Oil Producers Association (Patrimonio Comunal Olivarero) (Spain)

## **Funder(s)**

**Funder type**

Hospital/treatment centre

**Funder Name**

The Carlos III Health Institute (Instituto de Salud Carlos III) (Spain) - Fondo de Investigacion Sanitaria (FIS-FEDER)

## **Results and Publications**

**Individual participant data (IPD) sharing plan**

## IPD sharing plan summary

Not provided at time of registration

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/07/2010		Yes	No