ISRCTN53283428 https://doi.org/10.1186/ISRCTN53283428

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

Submission date 16/06/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 28/07/2009	**Overall study status** Completed	
Last Edited 17/08/2010	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Ms Anna Blasco

Contact details
PRBB
IMIM-Hospital del Mar
URLEC
Dr. Aiguader, 88
Barcelona
Spain
08003
ablasco@imim.es

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

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

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 measure
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.

Secondary outcome measures
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.

Overall study start date
20/10/2007

Completion date
20/10/2008

Eligibility

Key inclusion criteria
Healthy volunteers aged 20 - 50 years old, either sex

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
90 volunteers (45 men and 45 women)

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^2)
6. Hypercholestrolaemia 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)

Sponsor details
C/Prim, 12
Madrid
Spain
28004
info@pco.es

Sponsor type
Industry

Website
http://www.pco.es/

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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2010		Yes	No