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The effect of phenolic content of olive oil on ischaemic reactive hyperaemia in pre-hypertensive subjects

Submission date 18/01/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 02/02/2010	**Overall study status** Completed	
Last Edited 26/08/2014	**Condition category** Circulatory System	

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
N/A

Study information

Scientific Title
Effects of virgin olive oil enriched with phenolic compounds on blood pressure and endothelial function: a randomised double-blind crossover controlled trial

Acronym
OLIPA study

Study objectives
Increased antioxidant capacity exerted by phenolic compounds improved endothelial function leading to reduced blood pressure in postprandial state.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local medical ethics committee (Comité d'Ètica d'Investigació Clínica Hospital Universitari Sant Joan, Reus) approved, 24/04/2008, ref: 08-04-24/4proj5

Study design
Randomised double-blind crossover controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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
Ischaemic reactive hyperaemia/blood pressure

Interventions
All participants will follow a stabilisation period of 1 week with a low saturated fat diet. The day before to the postprandial test was followed by a polyphenol-free diet. Participants will be randomised individually between two postprandial tests:
1. Virgin olive oil. This will have a polyphenol content of 332.63 mg/kg (or 332.63 ppm measured by HPLC-DAD), an amount similar to oils in the area.
2. Virgin olive oil enriched with polyphenols. This will be enriched with polyphenols from defatted olive paste, which increase the concentrations up to three times, reaching a total content of 1008.14 mg/kg (or 1008.14 ppm measured by HPLC-DAD). These oils are prepared by the research group from Universitat de Lleida.

Participants will be provided with 80 g of bread containing 30 ml of the oil they have been allocated to. For 300 minutes after ingestion, participants will rest and may only drink water. One week later, participants will take the other investigational product in the same manner as before.

Diet monitoring will be conducted through a 3-day dietary record, in weeks 1 and 2. Participants are advised to maintain their usual physical activity and are monitored by a physical activity questionnaire.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Virgin olive oil enriched with phenolic compounds

Primary outcome measure
1. Blood pressure, measured at baseline and 120, 240 and 300 minutes on each study day
2. Endothelial function and activation biomarkers, measured at baseline and 120 , 240 and 300 minutes on each study day

Secondary outcome measures
Difference between the two oils (from baseline to 120, 240 and 300 minutes) of the following parameters:
1. The concentration of phenolic compounds in plasma, up to 300 minutes
2. Lipoproteins (total cholesterol, low density lipoprotein [LDL] cholesterol, high density lipoprotein [HDL] cholesterol, triglycerides) and apolipoproteins A1 and B100
3. Liver function tests
4. Angiotensin converting enzymes (ACE) inhibitory activity
5. Biomarkers of oxidation (LDL oxidised lipoperoxides, 8-epi-prostaglandin F2)
6. Biomarkers of inflammation (interleukin 6, high sensitivity C-reactive protein [hsCRP])
7. Antithrombotic activity biomarkers (plasminogen activator inhibitor-1 [PAI-1], factor VII antigen [FVIIag], activated factor VII [FVIIa])
8. Endothelial activation biomarkers (vascular cell adhesion molecules [VCAMs], intercellular adhesion molecules [ICAMs], e-selectin)
9. The relationship between nitrate (NO3)/nitrite (NO2)
10. Glycaemia and insulin resistance by Homeostatic Model Assessment (HOMA) index
11. The genetic profile of genes involved in endothelial function and blood pressure

Overall study start date
28/01/2009

Completion date
31/03/2010

Eligibility

Key inclusion criteria

1. Healthy volunteers aged 18 to 75 years, either sex
2. Systolic blood pressure levels upper or equal 120 to 159 mmHg and/or diastolic blood pressure upper or equal 80 to 99 mmHg without antihypertensive treatment

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30 (15 men and 15 women)

Key exclusion criteria
1. Low density lipoprotein cholesterol (LDL-c) levels upper 189 mg/dL
2. Triglycerides upper 350 mg/dL (the threshold level to determine LDL-c by the Friedewald formula)
3. Chronic alcoholism
4. Body mass index (BMI) upper 30 kg/m^2
5. Statin treatment prior to initiating the trial and would not have left at least 2 months before starting the study
6. Antihypertensive treatment prior to initiating the trial and would not have left at least 2 months before starting the study
7. Having diabetes mellitus (if you develop a blood glucose, fasting, upper 126 mg/dL, should be repeated and confirmed)
8. Renal disease (plasma creatinine levels upper 1.4 mg/dL for women and upper 1.5 mg/dL for men
9. Having acute infectious diseases, malignancies, severe liver insufficiency, chronic respiratory insufficiency or associated endocrine diseases
10. Other conditions such as special nutritional requirements or medications that may affect lipid metabolism or blood pressure
11. Participate or participating in a clinical trial in the last 3 months
12. Incapacity to continue in the study
13. History of gastrointestinal disease that can impair the absorption of nutrients
14. Suicide attempt

Date of first enrolment
28/01/2009

Date of final enrolment
31/03/2010

Locations

Countries of recruitment
Spain

Study participating centre
C/ Sant Llorenç, 21
Reus
Spain
43201

Sponsor information

Organisation
Rovira i Virgili University (Spain)

Sponsor details
Health Science Faculty
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Sponsor type
University/education

Website
http://www.urv.net/

ROR
https://ror.org/00g5sqv46

Funder(s)

Funder type
Government

Funder Name
Spanish Ministry of Education and Science (Spain) (ref: AGL2005-07881-C02-01/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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	15/01/2015		Yes	No