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The effect of olive oil on oxidative damage in European populations

Submission date	Recruitment status	[_] Prospectively registered
08/12/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
06/01/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
03/07/2015	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.kepka.org/eurolive

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
QLK1-CT-2001-00287

Study information

Scientific Title
The effect of olive oil on oxidative damage in European populations

Acronym
EUROLIVE

Study objectives
Olive oil consumption will provide benefits on oxidative damage. These benefits will increase with the phenolic content of the olive oil.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised crossover controlled trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Oxidative damage to lipids

Interventions
Three types of olive oil with differences in their phenolic content (25 ml per day). Intervention periods of three weeks separated by two week-washout periods.

Intervention Type
Other

Primary outcome measure
Oxidative damage to lipids and Deoxyribonucleic Acid (DNA)

Secondary outcome measures
Lipids and lipoprotein metabolism

Overall study start date
20/09/2002

Completion date
30/06/2003

Eligibility

Key inclusion criteria
Healthy, non-smoking, voluntary men aged 20 - 60 years

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Male

Target number of participants
180 participants from 6 Centres of 5 European countries

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 32 kg per m^2)
6. Hypercholestrolemia greater than 8.0 mmol per litre or dyslipemia therapy indication
7. Diabetes
8. Multiple allergies
9. Celiac or other intestinal diseases
10. Any condition that limits the mobility of the subject making study visits impossible
11. Life threatening illnesses such as cancer or a severe disease with a less than 3-year expectancy
12. Other diseases or conditions that could worsen adherence to the measurements or treatments
13. Vegetarians and people following special diets

Date of first enrolment
20/09/2002

Date of final enrolment
30/06/2003

Locations

Countries of recruitment
Spain

Study participating centre
Institut Municipal d´Investigació Mèdica (IMIM)
Barcelona
Spain
08003

Sponsor information

Organisation
European Commission, Research Directorate

Sponsor details
Rue de la Loi 200
Brussel
Belgium
B-1049
+32 (0)2 296 18 65
callum.searle@cec.eu.int

Sponsor type
Other

Website
http://www.cordis.lu

ROR
https://ror.org/00k4n6c32

Funder(s)

Funder type
Government

Funder Name
European Commission (Belgium) (ref: QLK1-CT-2001-00287)

Alternative Name(s)

European Union, Comisión Europea, Europäische Kommission, EU-Kommissionen, Euroopa Komisjoni, Ευρωπαϊκής Επιτροπής, Европейската комисия, Evropské komise, Commission européenne, Choimisiúin Eorpaigh, Europskoj komisiji, Commissione europea, La Commissione europea, Eiropas Komisiju, Europos Komisijos, Európai Bizottságról, Europese Commissie, Komisja Europejska, Comissão Europeia, Comisia Europeană, Európskej komisii, Evropski komisiji, Euroopan komission, Europeiska kommissionen, EC, EU

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

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	05/09/2006		Yes	No
Results article	results	01/05/2012		Yes	No
Results article	results	01/08/2015		Yes	No