# The effect of olive oil on oxidative damage in European populations

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

#### Contact name

Dr María Isabel Covas

#### Contact details

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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, Εвροπεйската 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