ISRCTN93136746 https://doi.org/10.1186/ISRCTN93136746

Bioavailability of virgin olive oil bioactive compounds and medium term impact on biomarkers of health

Submission date
02/06/2014

Recruitment status
No longer recruiting

Registration date
09/07/2014

Overall study status
Completed

Last Edited
19/02/2015

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Virgin olive oil is widely used in Mediterranean food and has been associated with health benefits such as protection against heart disease. For many years, the beneficial properties of olive oil were attributed to a type of fat named oleic acid. Besides containing high quantities of oleic acid, some olive oils contain small molecules called phenolic compounds, which are known as natural antioxidants. Little is known about the fate of these compounds in the body once they are consumed, or where they do to influence health. This study aims to find out the contribution of phenolic compounds present in virgin olive oil to the prevention of diseases and promotion of health using new biomarker techniques (a biomarker is a small molecule acting as a reporter for health and disease).

Who can participate?
Healthy adults, aged 18-75, who are not allergic to olive products.

What does the study involve?
Your body weight, height, waist circumference and blood pressure will be recorded and you will fill in a questionnaire to help us establish your intake of foods rich in phenolic compounds. During the 6-week study period, you will be randomly allocated to take a daily dose of olive oil (20 ml) with either a high or low polyphenolic content, to be consumed uncooked. At the beginning, middle and end of the study, participants will be asked to keep a record of the food eaten the day before the visit, to collect a spot urine sample in a small tube (second urine of the day) and to provide a blood sample. We will measure, in urine and blood, the levels of small molecules (biomarkers) that are related to heart and kidney health, as well as the way food is digested, transformed in the body and excreted.

What are the possible benefits and risks of participating?
There are no benefits or risks associated with taking part in the trial.

Where is the study run from?
Not provided at time of registration.

When is the study starting and how long is it expected to run for?
The study started in July 2012 and ran for 6 weeks.

Who is funding the study?
University of Lisbon (Portugal).

Who is the main contact?
Dr William Mullen
william.mullen@glasgow.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr William Mullen

Contact details
Institute of Cardiovascular and Medical Sciences
Joseph Black Building
University of Glasgow
Glasgow
United Kingdom
G12 8QQ

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2012071

Study information

Scientific Title
Bioavailability of virgin olive oil bioactive compounds and impact of a 6-week supplementation on biomarkers of coronary artery disease, chronic kidney disease or diabetes

Study objectives
Can a 6-week supplemetation of olive oil with either a high or low polyphenolic content alter proteomic biomarkers of coronary artery disease, chronic kidney disease or diabetes?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics committee of the University of Glasgow, College of Medical, Veterinary and Life Sciences, 31/08/2012, ref. 2012071.

Study design
Double-blind parallel supplementation study with low and high polyphenolic olive oil

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet
Patient information is available as a leaflet that can be obtained by contacting Dr Emilie Combet by telephone on 0141 201 0768 or via e-mail at emilie.combetaspray@glasgow.ac.uk, or Dr Bill Mullen on 0141 330 6210 (bill.mullen@glasgow.ac.uk). A third party who will be able to advise on the general research process is Professor Mike Lean (mike.lean@glasgow.ac.uk).

Health condition(s) or problem(s) studied
Risk of coronary artery disease, chronic kidney disease and diabetes

Interventions
66 healthy volunteers will be randomly allocated into one of two groups and asked to consume 20 ml of olive oil per day for 6 weeks.

Group 1 will be given olive oil with a high polyphenolic content.
Group 2 will be given olive oil with a low polyphenolic content.

Blood and urine samples will be collected the day before the study starts and also after 3 weeks and at the end of the study. Blood pressure and weight will be recorded at these visits too.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Proteomic urinary biomarkers of coronary artery disease, chronic kidney disease and diabetes. These will be measured after 3 weeks, the mid point and after 6 weeks, the end of the study.

Secondary outcome measures
Plasma-based biomarkers of heart disease and blood pressure. These will be measured after 3 weeks, the mid point and after 6 weeks, the end of the study.

Overall study start date
01/07/2012

Completion date
31/08/2012

Eligibility

Key inclusion criteria
Healthy adults, aged 18-75 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
66

Key exclusion criteria
1. Those allergic to olive products
2. Currently taking medication (other than the contraceptive pill)
3. Have taken antibiotics in the last 3 months
4. Have received or are receiving treatments for any chronic gut disease
5. Is pregnant, trying to conceive, or lactating

Date of first enrolment
01/07/2012

Date of final enrolment
31/08/2012

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Institute of Cardiovascular and Medical Sciences
Glasgow
United Kingdom
G12 8QQ

Sponsor information

Organisation
University of Glasgow (UK)

Sponsor details
c/o Dr WIlliam Mullen
Institute of Cardiovascular and Medical Sciences
Joseph Black Building
Glasgow
Scotland
United Kingdom
G12 8QQ

Sponsor type
University/education

ROR
https://ror.org/00vtgdb53

Funder(s)

Funder type
University/education

Funder Name
University of Lisbon, in collaboration with the Sovena company (Portugal)

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	01/01/2015		Yes	No