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Effect of extra virgin olive oil versus refined olive oil in alleviating obesity-induced inflammation in obese people with pre-diabetes

Submission date
31/12/2019

Recruitment status
No longer recruiting

Registration date
10/02/2020

Overall study status
Completed

Last Edited
04/07/2023

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
The purpose of this clinical trial is to verify whether the consumption of extra virgin olive oil (which has high levels of polyphenols) improves the inflammatory profile in people with low-grade inflammation, also known as meta-inflammation, and that it is common in people obese with prediabetes, compared to an olive oil with tiny amounts of polyphenols.
Likewise, other important aspects for health such as body weight and metabolic profile (fasting glucose, insulinemia, insulin resistance, beta cell functionality, glycosylated hemoglobin, lipidemia, etc.) will also be evaluated.
The improvement of these parameters is associated with a delay in the development of cardiovascular disease and diabetes, and could lead to the use of extra virgin olive oil, high in polyphenols, as a substitute for the natural source of dietary fat, as well as elaborate functional foods based on extra virgin olive oil.

Who can participate?
Adults (45 – 60 years old) who are obese (BMI 30 – 40) not diagnosed with diabetes

What does the study involve?
Participants will be randomly allocated to receive a one-month consumption of one type of olive oil (extra-virgin olive oil or refined olive oil) followed by a wash period of 15 days and a second one-month consumption of the second olive oil (refined olive oil or extra-virgin olive oil)

What are the possible benefits and risks of participating?
Expected benefits could include amelioration of metabolic alterations, such as fasting glucose, insulin resistance and weight loss. There are no expected risk for participants as they are just asked for substituting cooking oil at home for the one provided (blinded commercially available olive oil with low/high polyphenols content).

Where is the study run from?
Hospital Regional de Malaga, Spain

When is the study starting and how long is it expected to run for?
March 2018 to June 2019

Who is funding the study?
1. Consejería de Salud y Familias, Junta de Andalucía (Ministry of Health and Families, Junta de Andalucía), Spain
2. Instituto de Salud Carlos III, Ministerio de Sanidad, Gobierno de España (Carlos III Health Institute, Ministry of Health, Government of Spain)

Who is the main contact?
Dr Francisco-Javier Bermudez-Silva
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
PI-0247-2016

Study information

Scientific Title
Randomized double-blind cross-over interventional trial to assess the beneficial effects of extra-virgin olive oil versus refined olive oil in metainflammation

Acronym
APRIL

Study objectives

Extra virgin olive oil improves obesity-related meta-inflammation in obese people with pre-diabetes when compared to refined olive oil

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 29/11/2017, Ethics Committee for Clinical Research (CEI) of Malaga (Ethics Research Committee Provincial de Málaga, 7ª planta, Pabellón A, Hospital Regional Universitario, Avda Carlos Haya s/n, 29010-Malaga, Spain; + 34 951291977; eticainvestiga.hch.sspa@juntadeandalucia.es), ref:11/2017-PI1

Primary study design
Interventional

Study design
Randomized single-centre double-blind cross-over interventional trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Obesity and pre-diabetes

Interventions
One-month consumption of one type of olive oil (extra-virgin olive oil or refined olive oil) followed by a wash period of 15 days and a second one-month consumption of the second olive oil (refined olive oil or extra-virgin olive oil)

Randomisation process: 1:1 randomisation without stratification.

Data collection:
The nurse in charge of the study collects during each visit data on social status, habits, clinical, nutritional habits and semi-quantitative food frequencies, physical activity and anthropometrics. Fasting urine and blood samples are also collected, for measuring standard biochemical parameters, inflammatory parameters, oxidative stress markers, hormones, polyphenols levels. Patients are asked to bring with them a faeces sample for microbiota analysis.

Intervention Type
Supplement

Primary outcome(s)
Inflammatory markers measured from serum/plasma samples by multiplex assay (IL-6, IL-1B, TNF-a, Leptin, adiponectin, CXCL-1, IFN-g, IL12p40, IL-4, IL-10, IL-13, IL-RA, hs-CRP) before and after each treatment

Key secondary outcome(s)
1. Body weight (kg) measured before and after each treatment
Measured from serum/plasma samples by multiplex assay before and after each treatment:
2. Metabolic status (fasting glucose, insulinemia, HOMA-IR, HOMA-B, HbA1C, lipid profile)
3. Standard biochemical analysis (Urea, uric acid, albumin, Fe2+, ferritin, bilirrubin, FA, Vit D,

hemogram)
4. Oxidative status (LOOH, AOPP, TAS, Total thiol, Glutatione reductase)
5. Lipidomic profile by DOSY-NMR
6. Microbiota profile

Completion date
13/06/2019

Eligibility

Key inclusion criteria
1. Adult (40 - 65 years old)
2. Obese: BMI 30 - 40 kg/m²
3. Glycated hemoglobin (HbA1c): 5.7 - 6.4
4. Signed informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
40 Years

Upper age limit
65 Years

Sex
All

Total final enrolment
91

Key exclusion criteria
1. Previous diagnosis of diabetes mellitus
2. Pregnant women
3. Diagnosis of some type of neoplasia
4. Inflammatory diseases in progress (Crohn's disease, ulcerative colitis, arthritis) and/or anti-inflammatory treatments
5. Women in hormone replacement therapy
6. Eat regularly more than 3 meals/week away from home (lunch or dinner, unless it is homemade food prepared with the provided oil)

Date of first enrolment
08/03/2018

Date of final enrolment
27/02/2019

Locations

Countries of recruitment
Spain

Study participating centre
Hospital Regional de Malaga
Plaza del Hospital Civil s/n Pabellon 2
Sotano Lab Investigacion-Hormonas
Malaga
Spain
29009

Sponsor information

Organisation
Fundación Pública Andaluza para la Investigación de Málaga en Biomedicina y Salud

ROR
https://ror.org/002nw1r81

Funder(s)

Funder type
Government

Funder Name
Consejería de Salud y Familias, Junta de Andalucía

Funder Name
Instituto de Salud Carlos III

Alternative Name(s)
SaludISCIII, InstitutodeSaludCarlosIII, Instituto de Salud Carlos III | Madrid, Spain, Carlos III Institute of Health, Institute of Health Carlos III, Carlos III Health Institute, La misión del Instituto de Salud Carlos III (ISCIII), ISCIII

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Spain

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request. Dr. Javier Bermudez-Silva, (javier.bermudez@ibima.eu); specifically, raw data for published variables; data are expected to be available late 2020/early 2021 and during at least 10 years; data will be shared with researchers from public/non-profit research organizations upon reasonable request, allowing analysis of health variables related to the aims of this trial; consent from patients was obtained, patients were code converted, being the principal investigator the only person who guards the file (protected by password) encoding personal data of the participants; samples will be stored in the public biobank of the Consejeria de Salud de la Junta de Andalucía (Biobanco del Sistema Sanitario Público de Andalucía (BBSSPA), biobancomalaga.fps@juntadeandalucia.es) under specific MTA agreement between BBSSPA and the principal investigator and signed consent from patients; surplus samples will be available to other researchers from public/non-profit research organizations upon reasonable request to the principal investigator (Dr. Javier Bermudez-Silva, javier.bermudez@ibima.eu); Biological samples and associated clinical data will be used in accordance to Ley 14/2007, of 3rd July, of Biomedical Research (Spain); Personal data collected will be considered confidential and managed according to Ley Orgánica 15/1999, of 13th December (Spain), of personal data protection.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		27/06/2023	04/07/2023	Yes	No
Participant information sheet	Sample donation informed consent in Spanish version v.03	30/06/2017	28/04/2023	No	Yes
Participant information sheet	Spanish	31/10/2017	28/04/2023	No	Yes
Preprint results		29/03/2023	31/03/2023	No	No
Protocol file	version 3	28/11/2017	13/09/2022	No	No