ISRCTN12535644 https://doi.org/10.1186/ISRCTN12535644

Is olive leaf extract useful to treat mild hypertension?

Submission date	Recruitment status	[_] Prospectively registered
20/06/2018	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
16/07/2018	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
04/01/2024	Circulatory System	

Plain English summary of protocol

Background and study aims
The most prevalent disease in adults is hypertension (high blood pressure). The guidelines propose to start treatment in primary care with healthy lifestyle advice and medication if blood pressure is not normalized or the patient has a high cardiovascular (heart disease) risk. The olive leaf contains oleuropein, which has traditionally been used to lower blood pressure. The aim of this study is to measure blood pressure in adults with hypertension treated with olive leaf extract.

Who can participate?
Patients aged 25-65 with hypertension

What does the study involve?
Participants are randomly allocated to take either two placebo (dummy) tablets once daily or two tablets of olive leaf extract once daily for 30 days, followed by a 15-day break, after which they take the other tablets for 30 days. Blood pressure is measured before and after each treatment period. A blood sample is taken before the first treatment period, during the 15-day break, and after the second treatment period. Each participant is asked on a weekly basis about the palatability of the tablets.

What are the possible benefits and risks of participating?
No direct benefits are expected for the participants. It is possible that the blood pressure measurement provides useful information for the subsequent treatment of these patients. Some cases of mild digestive intolerance and bitter taste have been reported with olive leaf extract. There is no serious risk to health.

Where is the study run from?
CAP Ernest lluch (Spain)

When is the study starting and how long is it expected to run for?
February 2017 to November 2018

Who is funding the study?
METHARISC Group

Who is the main contact?
1. Prof. Gabriel Coll de Tuero
gcolld@comg.cat
2. Ms Rufina Espín Sanchez
st525357@gmail.com

Contact information

Type(s)
Scientific

Contact name
Prof Gabriel Coll de Tuero

ORCID ID
https://orcid.org/0000-0001-7578-9569

Contact details
Maluquer Salvador,11
Girona
Spain
17002
+34 (0)972421498
gcolld@comg.cat

Type(s)
Scientific

Contact name
Ms Rufina Espín Sanchez

ORCID ID
https://orcid.org/0000-0002-8873-3465

Contact details
Canigó,9
Vilamalla
Spain
17469
+34 (0)677871273
st525357@gmail.com

Additional identifiers

ClinicalTrials.gov (NCT)
NCT12535644

Protocol serial number
P17/038

Study information

Scientific Title
Mild hypertension treated with olive leaf extract clinical trial

Study objectives
1. The treatment of mild essential hypertension (HT) with a brief advice on healthy lifestyle and leaf olive extract at doses recommended by the European Medicines Agency (EMA) will reduce the systolic and diastolic blood pressure significantly.
2. The treatment of the Mild HT with a brief advice on lifestyle modifications and olive leaf extract will allow a better control of blood pressure in a higher percentage than the group that receives only brief advice about lifestyle modifications.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 10/10/2017, Comitè Ètic d´Investigació Clínica IDIAP (Gran Via Corts Catalanes, 587, Barcelona, 08007, Spain; +34 93 482 41 24; idiap@idiapjgol.org), ref: Protocol P17/038

Primary study design
Interventional

Study design
Randomized cross over double-blind trial

Study type(s)
Treatment, Efficacy

Health condition(s) or problem(s) studied
Hypertension

Interventions
From the population of Figueres city a sample population of 48 individuals will be extracted, by simple random sampling, these will be randomized into two groups A and B:

A. OLE, marketed under the name Olive Oil extract 20% (oleuropein Sura Vitasan 60 capsules, containing 1000 mg extract and 20% oraloleic)
B. Placebo with the same appearance

Each of the participants will receive 2 placebo tablets each day (once daily) or 2 tablets of active principle each day (once daily) of olive leaf extract with 20% oleuropein (1000 mg). Each participant will take the active treatment or placebo for 30 days, followed by a 15-day washout period, after which they will take placebo or active treatment. Each participant will be randomized to start the first period with placebo or active treatment.

A blood sample analysis will be done before the 1st exposure, during the washout period (intermediate), and after the 2nd exposure has finished. Each participant will be asked on a weekly basis for their palatability.

Intervention Type
Supplement

Primary outcome(s)
Ambulatory blood pressure (in mmHg) measured at the beginning and end of each treatment period (placebo or active treatment)

Key secondary outcome(s)
Hypertension control (BP < 140/90 mmHg; in percentage) measured at the beginning and end of each treatment period (placebo or active treatment)

Completion date
31/10/2019

Eligibility

Key inclusion criteria
1. Men and women aged 25-65
2. Diagnosed with essential hypertension grade 1
3. Without allergy to the components of the leaf extract of the olive or the capsule
4. Low CV risk
5. Who don't take hypertension treatment a month before inclusion
6. Do not have a target organ lesion and/or chronic illnesses (kidney, respiratory, cardiac, liver, haematological, infectious, etc) according to the European Guide for the management of the HTA ESH ESC 2013
7. Informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
25 Years

Upper age limit
65 Years

Sex
All

Total final enrolment
24

Key exclusion criteria
1. People with HTA grade 2 and 3
2. Grade 1 with a moderate CV risk, or high or very high according to the ESH-ESC 2013 Guidelines
3. With LOD or with subclinical vascular disease
4. With cognitive or idiomatic difficulty in fulfilling the instructions
5. Having chronic illnesses
6. Taking treatments that interfere or contraindicate the administration of the components of the olive leaf
7. Lactose intolerance
8. Pregnancy or breastfeeding

Date of first enrolment
15/06/2018

Date of final enrolment
30/12/2019

Locations

Countries of recruitment
Spain

Study participating centre
CAP Ernest lluch
Tramuntana, 2
Figueres
Spain
17600

Sponsor information

Organisation
Institut Universitari d'Investigació en Atenció primària Jordi Gol i Gorina (IdIAP)

ROR
https://ror.org/0370bpp07

Funder(s)

Funder type
Other

Funder Name
METHARISC Group

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Rufina Espín (st525357@gmail.com) from January 2019. The data will always be provided anonymized for reviews or meta-analysis whenever the principal investigators consider it appropriate. There are no legal restrictions to share this data as long as they are properly anonymized.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other unpublished results			04/01/2024	No	No
Thesis results			04/01/2024	No	No