The effect of olive leaf extract administration on cardiovascular health

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The objective of this study is to investigate the effect 8-week OLECOL supplementation on cardiovascular risk markers.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON44077

Source
ToetsingOnline

Brief title
The effect of olive leaf extract administration on cardiovascular health

Condition

- Other condition

Synonym
(borderline) hypercholesterolemia, high cholesterol; overweight, obesity

Health condition

Risicofactoren voor cardiovasculaire ziekten

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: BioActor BV,voedingsindustrie

Intervention

Keyword: blood lipids, cardiovascular health, olive, polyphenols

Outcome measures

Primary outcome

The primary efficady parameter is blood lipid profile, as assesed by blood levels of total cholesterol, HDL and LDL cholesterol and triglycerides.

Secondary outcome

Secondary objectives include the assessment of the effect of OLECOL on lipid peroxidation, platelet aggregation, advanced glycation end-products, blood pressure, liver function, glucose and insulin metabolism, intestinal inflammation, metabolic activity, microbiota composition, and gastrointestinal symptoms.

Study description

Background summary

Cardiovascular disease (CVD) is the leading cause of death in Europe. Although the mortality of CVD is decreasing lately, the burden of CVD morbidity, tracked by hospital discharge data, has tended to trend upward since the early 2000s. Current guidelines emphasize lifestyle recommendations to prevent the incidence of CVD, such as increasing physical activity and reducing weight in overweight and obese. However, medicines are needed if lifestyle changes are not enough. Nevertheless, the high costs and side effects of these drugs highlight the need for new cost-effective primary preventive measures to reduce the incidence of CVD.

Supplementation with OLECOL, an olive leaf extract standardized for its oleuropein content (>16%) may have beneficial effects on multiple biomarkers of CVD; a link between polyphenol intake and the improvement of lipid profiles, protection from low density lipoprotein (LDL) oxidation, atherosclerotic progression, hypertension, inflammation and endothelial dysfunction has been proposed. Furthermore, it will be determined whether a link between the

supplement intake and nonalcoholic fatty liver disease (NAFLD), glucose/insulin levels and intestinal inflammation and microbiota composition can be detected.

Study objective

The objective of this study is to investigate the effect 8-week OLECOL supplementation on cardiovascular risk markers.

Study design

This is a randomized, parallel, double-blind, placebo-controlled trial.

Intervention

Participants will receive a daily dose of OLECOL or placebo for a period of 8 weeks. Two capsules of OLECOL or placebo have to be ingested every day 30 minutes before the first meal with a glass of water.

Study burden and risks

There are different burdens volunteers can experience during the study. Burdens that volunteers can experience are the time spend on the study (subjects will have to invest approximately 6 hours in the study). Subjects will have to take OLECOL or placebo supplements once daily for a period of 8 weeks; the supplements are safe for human use. They have to follow a dietary and healthy regimen, and cannot use alcohol and abstain from physical exercise prior to the test days. Also, they will have to discuss their medical history with the investigator, fill in three times a 3-day food record and a maximum total of 234 mL blood will be sampled during the three study visits by venipuncture. This may lead to minor discomfort and can cause small and transitory hematoma/bruises to appear.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Healthy individuals, Age: 18-70 years, BMI 25-35 kg/m2, Total cholesterol levels * 5.0 mmol/L.

Exclusion criteria

* History of severe cardiovascular, respiratory, urogenital, gastrointestinal/hepatic, hematological/immunologic, HEENT (head, ears, eyes, nose, throat). Dermatological/connective tissue, musculoskeletal, metabolic/nutritional, endocrine, neurological diseases, allergy, major surgery and /or laboratory assessments that might limit participation in or completion of the study protocol.
* Diabetes
* Use of medication that might have influence on endpoints (e.g. cholesterol lowering medication, hypertensive medication)
* Administration of investigational drugs or participation in any scientific intervention study which may interfere with this study in the 180 days prior to this study
* Use of antibiotics in the 30 days prior to the start of the study
* Use of antioxidants, minerals and vitamin supplements available in pharmacies, drugstores, food markets or in alternative medicine
* Pregnancy, lactation
* Abuse of products (> 20 alcoholic consumptions per week and drugs)
* Smoking
* Weight gain or loss (> 3 kg in previous 3 months)
* High physical activity (>4.5 hours of running/week)
* History of any side effects towards intake of olives

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2016
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO

Date:	18-05-2016
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	27-06-2016
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL54513.068.15
Other	volgt, registratie bij clinicaltrials.gov