The effect of 12-week supplementation with olive leaf extract (OLE) on body composition and muscle strength, skin-aging and menopause-related quality of life in postmenopausal women (45-70 y); a randomized controlled trial.

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The aim of this study is to investigate the effect of 12-week of 250 mg/day of olive leaf extract (OLE) supplementation on body composition and muscle strength, skin-aging and menopause-related quality of life in post-menopausal women (45-70 y).

Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON53755

Source
ToetsingOnline

Brief title
FEMMED Study

Condition

- Other condition

Synonym
menopause

Health condition

post-menopause symptoms

Research involving
Human

Sponsors and support

Primary sponsor: BioActor BV
Source(s) of monetary or material Support: BioActor BV

Intervention

Keyword: body composition, olive leaf extract, polyphenols, postmenopausal

Outcome measures

Primary outcome

The primary aim of this study is to determine whether daily supplementation of

olive leaf extract over a 12-week period leads to a change in body composition.

Secondary outcome

The effects of 12 weeks of daily olive leaf extract supplementation, compared

to control, on the following parameters will be assessed:

Muscle strength assessed by handgrip test.

Skin elasticity and firmness as determined by a probe system

Self-assessed Skin, hair and nail quality as determined by VAS scale

questionnaire

Skin, hair and nail parameters as determined by an additional probe system

(C-Cube probe)

Postmenopause Symptoms as determined by MENQOL and HFI Questionnaires

Physical activity as determined by the International Physical Activity

Questionnaire (IPAQ)

Serum lipid profile, fasting glucose and insulin, myostatin and biomarkers of

collagen and elastin dynamics measured with ELISA

Dietary habits as assessed by a 3-day food record

Study description

Background summary

Menopause is associated with abdominal adipose tissue accumulation and the loss of muscle mass which causes a decrease in muscle strength. Moreover, the decrease in estrogens associated with menopause increases the risk of osteoporosis. The supplementation of oleuropein, the most abundant polyphenol found in olive tree leaves, can be an effective strategy to ameliorate body composition, due to its potential to attenuate the aging-induced decrease in protein content in muscles, to enhance thermogenesis in adipose tissue and to increase serum osteocalcin, a bone turnover marker.

Study objective

The aim of this study is to investigate the effect of 12-week of 250 mg/day of olive leaf extract (OLE) supplementation on body composition and muscle strength, skin-aging and menopause-related quality of life in post-menopausal women (45-70 y).

Study design

This study will be a randomized, double-blind, controlled trial based on a 12-week supplementation with olive leaf extract compared to control. In a parallel design each individual will follow either a 12-week supplementation with OLE (INT) or a 12-week cellulose supplementation (CON).

Intervention

250 mg/day supplementation with olive leaf extract for 12 weeks

Study burden and risks

In total, 64 participants will visit the site on four occasions (one screening, three test days) which requires a total time investment of approximately 6 hours. During the study, participants will undergo a DXA scan, undergo multiple measurements (handgrip test, skin hair and nail assessment, blood samples) and complete questionnaires about skin, hair and nail evaluation, menopause symptoms and habitual physical activity. 34,5 mL of blood will be collected

from each participant during the study. Participants will be asked to ingest one capsule a day for a supplementation period of 12 weeks.

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

Postmenopausal women (amenorrhea over 12 months) Age between 45-70 years Body mass index (BMI) < 35 kg/m2

Exclusion criteria

Use of hormone replacement therapy, use of supplements or

medication affecting main outcomes, smoking.

Study design

Design

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	07-02-2023
Enrollment:	86
Type:	Actual

Ethics review

Approved WMO Date:	10-11-2022
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	25-09-2023
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	18-01-2024
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	NL81363.068.22