Bioavailability of phenolics from olive leaf extract.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21153

Source
Nationaal Trial Register

Brief title
BO-PKA

Health condition

pharmacokinetics of oleuropein metabolites

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

Concentrations of oleuropein metabolites in plasma and urine over 24h upon single dose administration of olive leaf extract standardized on oleuropein.

Secondary outcome

1. Differences in pharmacokinetic profiles between pre- and postmenopausal women;

2. Activity of circulating oleuropein metabolites towards bone metabolism markers in ex vivo assay.

Study description

Background summary

N/A

Study objective

Bioactive metabolites of oleuropein are bioavailable in pre- and postmenopausal women.

Study design

Single dose study, with 24h collection of plasma and urine.

Intervention

Single dose administration of olive leaf extract, followed by blood and urine collection over period of 24h.

Contacts

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Eligibility criteria

Inclusion criteria

GROUP 1:

1. Premenopausal women between 18 and 75 years old;

2. No history of hormone-related disorders or surgical interventions affecting female hormone balance (e.g. ovariectomy);

3. Premenopausal women should be on monophasic oral anti conception and the test day should not be in the pause week or in the first 3 days of pill use;

4. Only non-smoking individuals can participate, who did not smoke during at least 6 months before the start of the study;

5. The participants are capable and willing to sign the Informed Consent Form at voluntary basis, after having received detailed information;

6. The volunteers are considered healthy based on their medical history as questioned by the investigator;

7. The volunteers do not intend to become pregnant prior to or during the study.

GROUP 2:

1. Postmenopausal women (between 18 and 75 years old) as determined by the principal investigator. The participants should be at least 2 years post menopausal;

2. During the last ten days prior to the test day, the subjects are not allowed to use hormones, medicinal products, food supplements, anti-osteoporosis medication or vitamins that can influence bone metabolism or the test product. Subjects are allowed to continue chronic use of other drugs, which do not influence the outcome of the study;

3. Only non-smoking individuals can participate, who did not smoke during at least 6 months before the start of the study;

4. The participants are capable and willing to sign the Informed Consent Form at voluntary basis, after having received detailed information.

Exclusion criteria

1. Clinically significant abnormal liver functioning (serum alanine and aspartate aminotransferase);

2. Clinically significant abnormal serum creatinin;

3. Abnormal BMI (i.e. lower than 18 or higher than 30);

4. Use of concomitant medications or supplements;

5. Blood donation during the last 4 weeks prior to the first dosing till 4 weeks after the last dosing.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2011
Enrollment:	16
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 37716
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3012
NTR-old	NTR3160
CCMO	NL38388.068.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON37716

Study results

Summary results
N/A