Bioavailability of phenolics from olive leaf extract.

Gepubliceerd: 22-11-2011 Laatst bijgewerkt: 19-03-2025

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

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21153

Bron
Nationaal Trial Register

Verkorte titel
BO-PKA

Aandoening

pharmacokinetics of oleuropein metabolites

Ondersteuning

Primaire sponsor: BioActor BV
Overige ondersteuning: Sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

N/A

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen

(Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-12-2011
Aantal proefpersonen:	16
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 37716
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A