Assessment of the bioavailability of phenolics from an orange peel extract

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

Summary

ID

NL-OMON39992

Source
ToetsingOnline

Brief title
Bioavailability of orange phenolics

Condition

- Other condition

Synonym
bioavailability

Health condition

geen aandoening, het onderzoek is gericht op biobeschikbaarheid

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: BioActor BV,BioActor BV, Maastricht

Intervention

Keyword: bioavailability, polyphenols

Outcome measures

Primary outcome

The primary aim of the study is to evaluate the bioavailability of hesperidin, the main flavonoid present in the orange peel extract, which was previously shown to have biological activity. Assessment and evaluation will be done by analyzing the plasma and urinary concentrations of the main study parameter: hesperidin and hesperitin in plasma and urine following a single oral consumption of the respective compositions and dosage forms. The main endpoint is the determination of the most effective dosage form of hesperidin. To do this, blood samples will be collected pre-dose and after 5, 15, 30 min, 1, 2, 3, 4, 6, 8, 10 and 24 h. Urine will be collected and pooled during the same time period.

Secondary outcome

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Study description

Background summary

Against the background of numerous detrimental effects of reduced sleep and sleep quality in the developed world, substances that are capable of improving sleep have been of growing interest. Especially natural products, e.g. for

functional foods and nutritional supplements, such as valerian extracts have been of interest. Valerian roots contain several polyphenolic compounds, some of which are identical to polyphenols found in citrus fruits, specifically hesperidin, linarin and apigenin. The present study focuses on hesperidin extracted from the peel of sweet oranges. Published studies have indicated that hesperidin, when administered intraperitoneally acutely prolonged sleep in rodents, while it exhibited anxiolytic effects when administered chronically over a four week time period orally. The positive effects of hesperidin on sleep are exerted by the intact molecule, while the main metabolite, hesperitin does not seem to exhibit potent effects. Hence the need to develop and test novel dosage forms that make hesperidin bioavailable by avoiding premature metabolization in the gut and liver, such as lozenges. Lozenges are absorbed in the mouth while capsules are ingested and absorbed in the gastrointestinal tract, which might lead to an improved absorption of the intact hesperidin molecule by administering it in the form of a lozenge. Furthermore, different types of hesperidin extract could influence the bioavailability.

Study objective

The present study aims to determine the bioavailability of hesperidin when micronized and non-micronized, when S-enantiomeric enriched and racemic, and when incorporated in a lozenge compared to a capsule, such that the appropriate dosage form can be chosen.

Study design

The cross-over study will be performed in 8 non-smoking adults. The intervention comprises oral intake of three different 500mg dosages: (1) HE with S:R ratio 1,5:1 in a capsule, (2) micronized HE with S:R ratio 4:1 in a capsule, and (3) micronized HE with S:R ratio 4:1 in a lozenge. Each subject will receive each dosage form on three separate days that are at least one week apart.

Intervention

The study will consist of 3 study days in which each subject will consume in randomized order one of the three dosage forms containing the orange peel extract at the beginning of the test day.

Study burden and risks

After an overnight fasting, a catheter is placed in the arm of each subject for repeated blood collection. Per study day, 11 times 8 mL blood sample will be taken. Each individual is instructed to collect his/her urine during the stay at the facility. The participants are asked to collect their urine for 24 hours after intake of the orange peel extract and deliver it the next day at the

facility. Furthermore, one more blood sample of 8 mL will be taken the next day at t=24h. The participants are asked not to change their normal dietary habits before the study period, except that they are instructed to avoid any citric fruits and other polyphenol-rich foods and dietary supplements, all sorts of alcohol, tea and vinegars as much as realistically possible for a period starting 3 days prior to the start of the study day. Participants will not benefit directly from participation.

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

Age 18-75y, generally healthy (i.e. no severe conditions based on medical assessment), non-smoking

Exclusion criteria

current pregnancy, extreme BMI (<18,5 or >25), clinically significant abnormal liver functioning, blood donation during the last 4 weeks prior to the first dosing

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	22-04-2013
Enrollment:	10
Type:	Anticipated

Ethics review

Approved WMO Date:	01-05-2013
Application type:	First submission
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	NL42846.068.12
Other	Volgt nog. Registratie bij NTR