The effect of citrus extract administration on markers of oxidative stress in elderly subjects

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The aim of this study is to investigate the effect of citrus extract supplementation on markers of oxidative stress in elderly.

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

Summary

ID

NL-OMON45776

Source
ToetsingOnline

Brief title
The effect of citrus extract on oxidative stress

Condition

- Other condition

Synonym
Elderly, older individuals

Health condition

Leeftijdsgerelateerde gezondheidsafname, zoals o.a. verhoogd risico op infectie

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: BioActor B.V.,Voedingsindustrie

Intervention

Keyword: anti-oxidant, citrus flavonoids, elderly, oxidative stress

Outcome measures

Primary outcome

The primary objective is to assess the effect of 4 weeks of daily citrus extract supplementation on blood biomarkers of oxidative stress in elderly subjects.

Secondary outcome

The effect of 4 weeks of daily 500 mg citrus extract supplementation on blood markers of inflammation.

The effect of daily citrus extract supplementation 500m on fecal markers of intestinal inflammation and immune function after 4 weeks of administration.

The effect of 500 mg citrus extract on fecal and oral microbiota composition and metabolic activity after 4 weeks of administration.

The effect of 500 mg citrus extract on stool frequency, stool consistency and GI complaints after 4 weeks of administration.

Study description

Background summary

Flavonoids are polyphenolic compounds with diverse beneficial biochemical effects, including anti-oxidative and immune-modulating activities. Furthermore, they can affect the microbiota composition and their metabolic

activity. Increased levels of oxidative stress and inflammation are encountered in the elderly population. Moreover, elderly have a lower antioxidant status when compared to younger age groups. Oxidative stress and inflammation are implicated in the pathogenesis of various diseases such as cardiovascular disease, neurodegenerative disorders and cancer. Administration of citrus flavonoids to the elderly population might decrease oxidative stress and inflammation and improve antioxidant status.

Study objective

The aim of this study is to investigate the effect of citrus extract supplementation on markers of oxidative stress in elderly.

Study design

This is a randomized, double-blind, placebo-controlled, cross-over trial in elderly subjects.

Intervention

Each subject will undergo two different intervention periods, during which daily citrus extract or placebo will be supplemented for four weeks. The order of intervention will be decided by a randomization procedure. Two capsules have to be ingested every day 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 spent on the study (subjects will have to invest approximately 8 hours in the study), subjects will have to take daily citrus extract or placebo supplements for a total period of 8 weeks (two periods of 4 weeks) and they have to follow a dietary and healthy regimen and cannot use alcohol and must abstain from physical exercise prior to the test days. Moreover, they will have to discuss their medical history with the investigator, fill in several questionnaires and a maximum total of 138 mL blood will be sampled during the four 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 70-85 years
* BMI < 30 kg/m2

Exclusion criteria

* History or actual status of severe cardiovascular, respiratory, urogenital, gastrointestinal/ hepatic, hematological/immunologic, HEENT (head, ears, eyes, nose, throat), dermatological/connective tissue, musculoskeletal, metabolic/nutritional, endocrine, neurological diseases, major surgery and/or laboratory assessments which might limit participation in or completion of the study protocol.
* Disease with a life expectancy shorter than 5 years
* Institutionalized (e.g. hospital or nursing home).
* Subjects with abnormalities in haematology which may interfere with the endpoints of the study (to be decided by the principle investigator)
* Self-admitted Inflammation, (viral) infection (e.g. HIV or hepatitis B)
* Subjects with an autoimmune disease (e.g. Rheumatoid arthritis)

* Subjects with intestinal disorders which may interfere with the endpoints of the study (to be decided by the principle investigator)
* Use of medication which may interfere with the endpoints of the study (to be decided by the principle investigator)
* Changes in medication that may significantly affect the study outcome (according to the investigator*s judgment) within 1 month prior to the start of the study.
* Use of investigational drugs or participation in any scientific intervention study which may interfere with this study (to be decided by the principle investigator) in the 180 days before the study
* Use of (dietary) supplements containing antioxidants, vitamins and minerals
* Smoking
* Weight gain or loss (> 3 kg in the previous 3 months)
* Excessive intake of foods with a high polyphenol concentration
* Use of pre-, pro- or synbiotics within 1 month prior to the start of the study
* Blood donation within 1 month prior to the start of the study
* Excessive alcohol consumption (>20 alcoholic consumptions per week)
* History of any side effects towards the intake of flavonoids or citrus fruits

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-09-2018
Enrollment:	44
Type:	Actual

Ethics review

Approved WMO Date:	27-08-2018
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
ClinicalTrials.gov	NCT03580447
CCMO	NL65863.068.18