The effects of citrus extract administration on gastrointestinal health

Published: 03-05-2017
Last updated: 15-04-2024

The aim of this study is to investigate the effect of citrus extract supplementation on markers for gastrointestinal health.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal inflammatory conditions
Study type	Interventional

Summary

ID

NL-OMON50647

Source
ToetsingOnline

Brief title
The effects of citrus extract on gastrointestinal health

Condition

- Gastrointestinal inflammatory conditions

Synonym
irritable bowel syndrome, spastic colon

Research involving
Human

Sponsors and support

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

Intervention

Keyword: citurs fruits, gastrointestinal health, polyphenols

Outcome measures

Primary outcome

The primary endpoint of this study is the evaluation of intestinal inflammation, measured by levels of fecal calprotectin

Secondary outcome

Secondary endpoints entail the evaluation of daily administration of citrus extract on metabolic activity (fecal markers), microbiota composition and functional capacity (fecal markers), immune system performance (blood markers), gastrointestinal symptoms (questionnaires), and oxidative stress markers (blood markers).

Study description

Background summary

Flavonoids are polyphenolic compounds with diverse beneficial biochemical effects, including anti-oxidative and immune-modulating activities that can affect intestinal inflammation. Furthermore, they can affect the microbiota composition and activity. Low-grade intestinal inflammation is thought to play a role in the pathophysiology of irritable bowel syndrome (IBS), and is reported in a subgroup of IBS patients. Administration of the flavonoid hesperidin to these patients might decrease intestinal inflammation and disease-related symptoms.

Study objective

The aim of this study is to investigate the effect of citrus extract supplementation on markers for gastrointestinal health.

Study design

This is a randomized, parallel, double-blind, placebo-controlled trial

Intervention

Participants will receive a daily dose of citrus extract or placebo for a period of 8 weeks. Two capsules of citrus extract or placebo 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 spend on the study (subjects will have to invest approximately 6 hours in the study). Subjects will have to take citrus extract or placebo supplements once daily for a period of 8 weeks; the supplements are safe for human use. They have to follow a dietary and healthy regimen, and cannot use alcohol and abstain from physical exercise prior to the test days. Also, they will have to discuss their medical history with the investigator, fill in several questionnaires and a maximum total of 84 mL blood will be sampled during the three study visits by venipuncture. This may lead to minor discomfort and can cause small and transitory hematoma/bruises to appear.

Contacts

Public
Universiteit Maastricht

Universiteitssingel 40
Maastricht 6229 ER
NL
Scientific
Universiteit Maastricht

Universiteitssingel 40
Maastricht 6229 ER
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients with IBS, Calprotectin levels 15-150 µg/g feces, Age 18-70 years, BMI < 35 kg/m2

Exclusion criteria

* Comorbidities that may influence gut microbiota composition or which might limit participation in or completion of the study protocol (to be decided by the principle investigator)
* Abdominal surgery interfering with gastrointestinal function (to be decided by the principle investigator)
* Use of immunosuppressive drugs within 3 months before study period
* Use of other medication interfering with endpoints
* Changes in medication that may significantly affect the study outcome according to the investigator*s judgment within 1 month prior to the study
* Changes in clinical activity scores within 3 weeks prior to the study
* Administration 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 prior to the study
* Use of dietary supplements containing antioxidants, minerals and vitamins
* Excessive intake of foods with a high polyphenol concentration
* Use of antibiotics within 3 months prior to the start of study
* Use of pre-or probiotics within 1 month prior to the study
* Use of oral corticosteroids within 1 month prior to the study
* Blood donation within 1 month prior to the study
* Known pregnancy or lactation.
* Excessive drinking (>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:	Parallel

Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-12-2017
Enrollment:	128
Type:	Actual

Ethics review

Approved WMO Date:	03-05-2017
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	01-06-2017
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	17-01-2018
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	18-02-2019
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	NL60605.068.17
Other	volgt, registratie bij clinicaltrials.gov