Combination chemoprevention of complex mixtures of fruits and vegetables

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

Summary

ID

NL-OMON45998

Source
ToetsingOnline

Brief title
CombiChem

Condition

- Other condition

Synonym
chronic diseases, non-communicable diseases

Health condition

chronische ziekten

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: MiFood

Intervention

Keyword: bioactive compounds, Combination chemoprevention, fruits and vegetables, molecular mechanisms

Outcome measures

Primary outcome

Main study parameters/endpoints:

- To measure differences at the level of different phenotypic markers of disease risk: oxidative DNA damage in ex-vivo treated lymphocytes, antioxidant capacity of blood plasma, excretion of lipid peroxidation products in urine, plasma levels of different markers for cardiovascular disease and type II diabetes, and changes in the retinal microvasculature.
- To measure whole genome gene expression analyses in order to provide more insight in to the underlying molecular mechanisms. Genes and involved molecular processes associated with the measured phenotypic markers will demonstrate a causal relationship between the particular intervention and the markers of disease risk.
- To measure the occurrence of 20 different polymorphisms related to disease risk in order to identify particular subgroups that will benefit more from a particular intervention.

Secondary outcome

- bioavailability of different phytochemicals in blood plasma

- Detemining white blood cell count

Study description

Background summary

People who eat sufficient amounts of fruits and vegetables as part of their daily diet have a reduced risk of a number of chronic diseases, such as cancer, cardiovascular disease and type II diabetes mellitus. There is ample scientific evidence suggesting that these health benefits are the consequence of the combined action of different phytochemicals present in fruits and vegetables. However, the number of studies in humans is limited. More research is needed to unravel the most optimal combination of phytochemicals in fruits and vegetables that can protect against disease risk. Furthermore, the underlying mechanisms by these phytochemicals exert their effect remain unclear. In addition, people might respond differently to dietary changes due to their genetic make-up. It was shown that subjects with specific genetic characteristics may benefit more from certain combinations of phytochemicals than others. More combinations of fruits and vegetables should be tested in humans with different genetic backgrounds at the level of appropriate phenotypic markers of effect, including whole genome gene expression changes in order to provide insight into the underlying molecular mechanisms. Therefore, the aim of the present human dietary intervention study is to evaluate the effect of various combinations of vegetables and fruit containing different complex mixtures of phytochemicals in healthy volunteers on the level of phenotypic markers of disease risk in combination with whole genome gene expression analyses, and taking genetic variability between subjects into account.

Study objective

The main objective of the human dietary intervention study is to investigate the beneficial health effects of food products containing various combinations of an equivalent of 400 grams vegetables and fruits in healthy volunteers. This will be evaluated in different subgroups with specific genetic characteristics (max. 20 SNPs) on the level of different phenotypical markers, combined with gene expression profiling.

Study design

This human dietary intervention study has a randomized controlled cross-over * repeated measures design, including only healthy volunteers. After a two week run-in period, subjects will be randomized into one of the 9 study groups. Each group will follow two intervention periods of two weeks in which at each period one of nine different food product containing different combinations of

vegetables and fruits will be consumed, separated by a one week washout period. At baseline and after each intervention period, blood and urine is collected, and a photograph is taken from the fundus of the right eye for analyses of markers of oxidative stress, DNA damage, biomarkers of cardiovascular disease risk and type II diabetes, gene expression analyses and determination of maximum 20 genetic polymorphisms.

Intervention

Nine different food products containing different combination of fruits and vegetables will be evaluated in this human dietary intervention study. Seven of these 9 different food products consist of a smoothie, containing 400 grams of vegetables and fruits which will be consumed during the day: Smoothies 1-4 contain a specific selection of vegetables and fruit resulting in an overrepresentation of a specific class of phytochemicals. Smoothies 5-7 will consist of a combination of the four different classes overrepresented in smoothies 1-4, with increasing biodiversity. Food product 8 and 9 will consist of a pearl which is a crouton-like product, consisting of a core of oats and riceflour, and will be either coated or non-coated with the most diverse mixture of vegetables and fruits as used in smoothie number 7. Each subject will be randomized into one of the nine study groups, which will start of a two week run-in period followed by two intervention periods of two weeks separated by a washout-period. At each intervention period, one of the nine different food products will be consumed. At baseline, and after each intervention period, blood and urine will be collected, as well as a photographic image of the fundus of the right eye will be taken.

Study burden and risks

Healthy volunteers will have to sign an informed consent and must follow a strict diet in consultation with a dietician. The food products contain different combination of vegetables and fruits, at the level of recommendations, which are freely available and are considered to be healthy. Participants will have to come to the university 8 times. The first visit only comprises signing of the informed consent and oral explanation of the study design by the principle investigator. At baseline, and after the first and second intervention period, subjects will come to the university after an overnight fast and donate urine and blood. Also a photograph of the fundus of the right eye is taken. In total, subjects will have to collect three times 24 hour urine, at 3 times 34 mL of blood divided over 4 vacutainers will be drawn, and 3 images of the fundus of the right eye will be taken. The remaining visits are for collection of the food products.The risk of collection of these samples is considered to be minimal. However, the studyperiod of 7 weeks is relatively and will have an impact on the daily life of the volunteers. This discomfort is expected to be moderate. During the whole study period, subjects have to keep track of their diet using a food diary.

Contacts

Public
Universiteit Maastricht

Universiteitssingel 50
Maastricht 6229ER
NL
Scientific
Universiteit Maastricht

Universiteitssingel 50
Maastricht 6229ER
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Healthy men and women aged between 18-60 years
BMI between 18.5-27 kg/m2

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- Alcohol abuse up to 6 months before participation in this research, i.e. more than 4 drinks on any single day and more than 14 drinks per week for men and more than 3 drinks on any single day and more than 7 drinks per week for women;
- Current presence of any diseases related to the gastrointestinal tract, kidney, liver, heart or

lungs;
- Current presence of type I or type II diabetes;
- Current presence of symptoms related to diseases of the gastrointestinal tract, i.e. vomiting, diarrhea or constipation, and altered stool, such as blood in stool;
- Current presence of diseases related to the endocrine or metabolic system;
- Current presence of anemia;
- HIV infection or hepatitis;
- Use of antibiotics and other medication (except contraceptives) over the last 3 months;
- Use of dietary supplements during the 3 months before start of the study;
- Known allergies for fruits and/or vegetables
- Current smokers and ex-smokers who stopped during the 3 months before start of the study;
- Vegetarians and vegans;
- Pregnant women;
- Sportsmen and sportswomen who are physically active for more than 8 hours per week
- Participants of other intervention studies during this intervention period.

Study design

Design

Study type: Interventional

Masking:	Double blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-03-2019
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO

Date:	19-12-2018
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

ID: 23386
Source: NTR
Title:

In other registers

Register	ID
Other	29706
CCMO	NL66118.068.18
OMON	NL-OMON23386