Het effect van voedingsproducten met verschillende combinaties van groenten en fruit op de gezondheid van de mens

The effect of food products containing different combinations of vegetables and fruits on human health

No registrations found.

Ethical review	Not applicable
Status	Other
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23386

Source
Nationaal Trial Register

Brief title
CombiChem

Health condition

Combination chemoprevention, chronic diseases, cancer, diabetes, cardiovascular disease,molecular mechanisms, synergisms,

Combinatie chemopreventie, chronische ziekten, kanker, diabetes, hartvaat ziekten, moleculaire mechanismen, synergie

Sponsors and support

Primary sponsor: Maastricht University

Source(s) of monetary or material Support: Company Mifood

Intervention

Outcome measures

Primary outcome

-The level of oxidative DNA damage in ex-vivo treated lymphocytes

-Oxidative stress parameters

-Cardiovascular risk parameter: changes in microcirculation

-Whole genome gene expression analyses

-Evaluation of the prevalence of different polymorphisms

Secondary outcome

Optional parameters:

The level of different plasma lipid levels such as cholesterol by measuring total cholesterol, high density lipoproteins (HDL), and low density lipoproteins (LDL), and triglycerides using standard kits;

- The level of plasma homocysteine by means of ELISA;

- Platelet activation by measuring platelet factor 4 and P-selectin in plasma using ELISA;

- Immune response markers, like TNF-, interleukin-6, and C-reactive protein, using ELISA;

- The level of fasting glucose and insulin levels in plasma in order to quantify insulin resistance and beta-cell function by means of Homeostatic model assessment (HOMA model).

- bioavailability of different phytochemicals in the different interventions measured in plasma

- white blood cell count

Study description

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 on the level of different phenotypical markers, combined with gene expression profiling.

Study design

3 timepoints:

- baseline

- post-intervention 1

- post-intervention 2

Intervention

A dietary intervention study will be performed to establish the beneficial health effects of 9 different food products, produced by MiFood (a company involved in food production industry (www.mifood.nl)), containing various combinations of phytochemicals from different combinations of vegetables and fruits. Seven of these 9 different food products will consist of a smoothie, containing different combinations of vegetables and fruits. Smoothies 1-4 will 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 botanical diversity. Per day, each subject will consume 4 bottles of smoothies spread over the day, containing an equivalent of in total 400 grams vegetables and fruits.The remaining two dietary interventions will test a crouton (also called pearl), consisting of a core of oats and rice flour, either coated or non-coated with the most diverse mixture of vegetables and fruits as used in dietary intervention number 7.

Contacts

Public
P.O. Box 616, School for Oncology and Developmental, Department of Toxicogenomics, Maastricht University Medical Centre +

S.G.J.
van Breda

6200 MD

Scientific

P.O. Box 616, School for Oncology and Developmental, Department of Toxicogenomics, Maastricht University Medical Centre +

S.G.J.
van Breda

6200 MD

Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

- Healthy men or women with a Body Mass Index (BMI) between 18.5 and 27;

- Between 18-60 years old.

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
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	01-01-2019
Enrollment:	200
Type:	Unknown

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 45998
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL7358
NTR-old	NTR7566
CCMO	NL66118.068.18
OMON	NL-OMON45998

Study results

Summary results
None