The effect of hesperidin administration on glucose / insulin metabolism

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To determine the effects of daily administration of hesperidin on glucose/insulin metabolism and intestinal health as assessed by an oral glucose tolerance test (OGTT), and investigation of lipid metabolism, blood pressure, heart rate, gut barrier...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Interventional

Summary

ID

NL-OMON42312

Source
ToetsingOnline

Brief title
The effect of hesperidin on glucose/insulin metabolism

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
metabolic syndrome, obesity, overweight

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: BioActor BV,industrie

Intervention

Keyword: glucose/insulin metabolism, hesperidin, metabolic syndrome, polyphenol

Outcome measures

Primary outcome

The primary objective of this study is to evaluate the efficacy of Cordiart* on glucose/insulin metabolism, as assessed by OGTT measurements, after 12 weeks of administration.

Secondary outcome

Secondary objectives:

- Determine the 12-week effect of Cordiart* on glucose/insulin metabolism by blood measurements (to calculate homeostasis model assessment of indulin resistance (HOMA-IR) and quantitative insulin sensitivity check index (QUICKI))
- Determine the 12-week effect of Cordiart* on lipid metabolism by blood measurements
- Determine the 12-week effect of Cordiart* on body composition by anthropometric measurements (BMI, waist-hip circumference)
- Determine the 12-week effect of Cordiart* on blood pressure and heart rate by measuring systolic and diastolic blood pressure and heart rate
- Determine the 12-week effect of Cordiart* on plasma biomarkers of low-grade inflammation (TNF-*, IL-6, FFA, Adiponectin, MDA, Glutation)
- Determine the 12-week effect of Cordiart* on gut barrier function by measuring plasma and fecal zonulin
- Determine the 12-week effect of Cordiart* on gut barrier function by

performing a sugar permeability test

- Determine the 12-week effect of Cordiart* on microbiota composition

Study description

Background summary

From epidemiological data it is observed the prevalence of overweight and the prevalence of illnesses such as metabolic syndrome and cardiovascular diseases have greatly increased over past decades. The metabolic syndrome represents a combination of cardio-metabolic risk determinants including obesity (central adiposity), insulin resistance, glucose intolerance, dyslipidemia and hypertension. This syndrome is defined as a multifactorial disorder involving hypertension (HTN), hyperglycemia and hyperuricaemia. Overweight is considered to be an important factor in the etiology of the metabolic syndrome as it contributes to insulin resistance, hyperglycemia, high serum cholesterol, low High-density Lipoprotein (HDL) cholesterol, HTN, chronic low-grade inflammation and it is associated with higher cardiovascular disease (CVD) risk. The interest in this syndrome lies on the increased risk of developing DM2 and cardio- and cerebrovascular diseases. Furthermore, under energy-rich conditions, the inflammatory potential of metabolically important tissues can be reactivated; the adipose tissue of obese individuals has been shown to produce higher levels of pro-inflammatory factors. High-fat diet-induced obesity is associated with alterations in microbial composition and mucosal structure/functions (ref); this can result in a vulnerable microbial barrier and increased permeability of the intestine. This decreased barrier function may lead to movement of intestinal bacteria and/or lipopolysaccharides (LPS) into the circulation with chronic systemic low-grade inflammation as a result and this chronic inflammation plays an important role in the development of many chronic metabolic diseases.
This plethora of diseases is correlated with genetic predisposition and unfavorable lifestyle, characterized by low physical activity combined with overconsumption of food. Its common fundamental pathogenic component is resistance to insulin.

Study objective

To determine the effects of daily administration of hesperidin on glucose/insulin metabolism and intestinal health as assessed by an oral glucose tolerance test (OGTT), and investigation of lipid metabolism, blood pressure, heart rate, gut barrier function and body composition in overweight subjects.

Study design

This is a randomized, double-blind, placebo-controlled study of parallel design.

Intervention

Participants will be randomly assigned to one of the intervention groups. One group will receive one daily dose of 500 mg Cordiart*, while the other group receives an identical looking placebo capsule for a period of 6 weeks. The capsules will have to be ingested with a glass of water (200 ml) every morning just before breakfast.

Study burden and risks

There are several burdens volunteers can experience during the study period. Upon inclusion, study procedures will take maximum 9 hours for each of the subjects. Subjects will visit the MUMC+ at five test days. Subjects will have to take 500 mg Cordiart* or placebo supplements before breakfast daily for a period of 12 weeks; the supplements are safe for human use. Participants are not allowed to eat hesperidin rich foods during the complete studie period. They also are not allowed to smoke. On days before test days study participants will have to abstain from physical exercise and cannot use alcohol, and they will have to come to the test days in fasted state. During the test days the following measurements will be performed:
- OGTT measurement (test day 2 and 5). This will take approximately 3 hours
- Venapunctures (maximum 176 ml)
- Collect feces (3 times)
- Collect 24 hours urine (2 times)
- Fill out food diary (2 times, during 3 days)
- Blood pressure- and heart rate measurements

Contacts

Public
Universiteit Maastricht

P. Debyelaan 25
Maastricht 6229 HX
NL
Scientific
Universiteit Maastricht

P. Debyelaan 25
Maastricht 6229 HX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Men/women, healthy human beings, age 18-65 and two of following criteria:
*Waist circumference: men > 102 cm / women > 88 cm
*Triglycerides: * 1.7 mmol/l
*HDL-cholesterol: men * 1.0 mmol/l / women * 1.3 mmol/l
*Systolic blood pressure: * 130 mmHg or diastolic blood pressure: * 85 mmHg
*Fasted serum glucose * 6.1 mmol/L

Exclusion criteria

Type 2 diabetes mellitus; gastroenterological diseases or abdominal surgery; cardiovascular diseases; cancer; liver or kidney malfunction; disease with life expectancy shorter than 5 years; self-admitted HIV-positive status; abuse of products such as alcohol (>20 alcoholic consumptions per week) or drugs; smoking; plans to lose weight or following a hypocaloric diet; weight gain or loss > 3 kg in previous 3 months; use of medication interfering with endpoints; use of antioxidants, minerals and vitamin supplements available in pharmacies, drugstores, food markets, or in alternative medicine; hormone replacement therapy; use of antibiotics in the 90 days prior to the start of he study; known pregnancy; lactation; history of side effects towards intake of flavonoids or citrus fruits; administration of investigational drugs or participating in any scientific intervention study which may interfere with this study (to be decided by principal investigator) in the 180 days prior to the study; blood donation within 3 months before study period; failure to comply prohibited intake of hesperidin containing food products during study period

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-01-2015
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	15-12-2014
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	13-04-2015
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	NL49510.068.14
Other	Volgt, registratie in clinicaltrials.gov

Study results

Date completed:	23-10-2015
Actual enrolment:	53