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# Study of the beneficial effects of a combination of food ingredients on cardiovascular risk factors in overweight subjects

**Submission date**
14/09/2017

**Recruitment status**
No longer recruiting

**Registration date**
15/09/2017

**Overall study status**
Completed

**Last Edited**
15/09/2017

**Condition category**
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

## Plain English summary of protocol

Background and study aims
The aim of this study is to test whether a combination of food ingredients can decrease cardiovascular (heart disease) risk factors by reducing visceral adiposity (abdominal fat), hypercholesterolemia (high blood cholesterol) and endothelial (blood vessel) dysfunction. These ingredients are based on extracts rich in polyphenols and non-digestible fibers already known individually for their health benefits.

Who can participate?
Overweight people aged 18 and over

What does the study involve?
Participants are randomly allocated to take either the study medication or a placebo (dummy) capsule twice a day, 2 capsules each time (4 capsules per day), for 3 months. Clinical data, blood samples and faeces samples are collected and the brachial artery is examined by ultrasound at the start of the study, at the end of the first, second and third months of treatment, and one month after the treatment has finished.

What are the possible benefits and risks of participating?
Treatment does not cause any adverse health effects. This study does not involve any risks apart from those related to a conventional blood collection procedure or possible gastrointestinal discomfort.

Where is the study run from?
CHU UCL Namur Godinne (Belgium)

When is the study starting and how long is it expected to run for?
May 2017 to May 2019

Who is funding the study?
Competitivity pole WAGRALIM (Public service of Wallonia region) (Belgium)

Who is the main contact?
Prof. Laurence Galanti
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# Contact information

### Type(s)
Scientific

### Contact name
Prof Laurence Galanti

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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
B039201733170

# Study information

### Scientific Title
Study of the beneficial effects of a combination of food ingredients on cardiovascular risk factors in overweight subjects

### Acronym
ADIPOSTOP

### Study objectives
Decrease of cardiovascular risk factors (waist circumference, BMI, inflammatory parameters, lipid balance and oxidative status, endothelial function, intestinal microbiota) by taking a new combination of food ingredients.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)

Comité d’éthique médicale de CHU UCL Namur, site Godinne (Ethics committee of CHU UCL Namur, Godinne), 11/07/2017, ref: CE Mont-Godinne: 79/2017

## Study design
Interventional single-center double-blind randomized placebo-controlled study

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Hospital

## Study type(s)
Prevention

## Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

## Health condition(s) or problem(s) studied
Overweight patients

## Interventions
Participants are randomized by sealed envelope block method:
1. Study medication (VERUM) capsule composition: pomegranate extract 163 mg, chitin-glucan 375 mg, siliciumdioxide 18 mg, magnesium stearate 18 mg
2. Placebo capsule composition: cellulose 500mg, silicium dioxide 18 mg, magnesium stearate 18 mg.

Medication is administered per oral twice a day, 2 capsules each time (4 capsules per day). Duration of treatment: 3 months.

Duration of the study - 4 months with 5 visits performed: V0 - at the beginning of the study, V1 - at the end of the first month of treatment, V2 - at the end of the second month of treatment, V3 - at the end of third (last) month of treatment, V4 - one month after the treatment has finished.

## Intervention Type
Supplement

## Primary outcome measure
1. Blood collection with blood analysis at V0, V1, V3, V4:
1.1. Inflammatory parameters at V0, V1, V3, V4:
1.1.1. C-reactive protein high-sensitivity (hsCRP), µg/ml, measured using turbidimetric method
1.1.2. Interleukin 6, pg/ml, measured using ELISA
1.1.3. Interleukin 8, pg/ml , measured using ELISA
1.1.4. Interleukin 10, µmol/l, measured using ELISA
1.1.5. Tumor necrosis factor α, pg/ml, measured using ELISA
1.1.6. Monocyte chemotactic protein 1, MCP1, pg/ml, measured using ELISA

1.2 Parameters of oxidative and endothelial function at V0, V1, V3, V4:
1.2.1. Vitamin A, mg/L, measured using UPLC
1.2.2. Vitamin E, mg/L, measured using UPLC
1.2.3. Vitamin C, mg/l, measured using HPLC
1.2.4. Coenzyme Q10, µg/l, measured using HPLC
1.2.5 β-carotene, ng/ml, measured using HPLC
1.2.6. Superoxide dismutase (SOD), U/ml, measured using enzyme assay
1.2.7. Glutathione peroxidase (GPX), U/ml, measured using spectrophotometry
1.2.8. Soluble vascular adhesion molecule 1 (sVCAM 1), ng/ml, measured using ELISA
1.2.9. Soluble intercellular adhesion molecule 1 (sICAM 1), ng/ml, measured using ELISA
1.2.10. Asymmetric dimethylarginine (ADMA), µmol/l, measured using ELISA
1.2.11. Cluster of differentiation 40 ligand (CD40-L), pg/ml, measured using ELISA
1.3. Lipid parameters at V0, V1, V3, V4:
1.3.1. Cholesterol, mg/dl, measured using reflectometry
1.3.2. High density lipoprotein (HDL), mg/dl, measured using reflectometry
1.3.3. Low density lipoprotein (LDL), mg/dl, measured using spectrophotometry
1.3.4. Triglycerides, mg/dl, measured using reflectometry
1.3.5. Lipoprotein a (LPa), g/l, measured using nephelometry
1.3.6. Apolipoprotein A1 (ApoA1), g/l, measured using nephelometry
1.3.7. Apolipoprotein B (ApoB), g/l, measured using nephelometry
1.3.8. Small density low density lipoprotein (Sd-LDL), nmol/ml, measured using ELISA
1.3.9. Anti-oxidized low density lipoprotein antibodies (anti ox-LDL ab), measured using ELISA

2. Endothelial function assessed by ultrasound examination of the brachial artery at V0, V1, V2, V3, V4:
2.1. Diameter baseline (D baseline), mm
2.2. Diameter maximum (D max), mm
2.3. Flow mediated dilatation (FMD), %

## Secondary outcome measures

1. Blood collection with confounding parameters analysis at V0, V1, V3, V4:
1.1. Glycaemia, mg/dl, measured using reflectometry
1.2. Glycated hemoglobin A1c (HbA1c), %, measured using chromatography
1.3. Glutamic oxaloacetic transaminase (GOT), UI/L, measured using enzyme assay
1.4. Glutamic-pyruvic transaminase (GPT), UI/L, measured using enzyme assay
1.5. Gamma-glutamic transaminase (GGT), UI/L, measured using enzyme assay
1.6. Iron, µg/dl, measured using reflectometry
1.7. Albumin (ALB), g/l, measured using reflectometry
1.8. Ferritin, µg/l, measured using immunoassay
1.9. Magnesium, mmol/l, measured using reflectometry
1.10. Uric acid, mg/dl, measured using reflectometry
1.11 Creatinine (CRS), mg/dl, measured using enzyme assay
2. Collection of feces for intestinal microbiota analysis (V0, V3) during randomization and at the end of treatment
3. Assessment of nutritional status (via questionnaire) and bioelectrical impedance analysis at V0, V1, V2, V3, V4:
3.1. Height, m
3.2. Weight, kg
3.3. Waist circumference, cm
3.4. Abdominal diameter, cm
3.5. Fat, %

3.6. Fat, kg
3.7. Body mass index (BMI)
3.8. Waist/hip ratio

### Overall study start date
01/05/2017

### Completion date
30/05/2019

## Eligibility

### Key inclusion criteria
1. Male and female
2. Aged at least 18 years
3. Caucasian type
4. 25<BMI <35 ± 5%
5. Stable patient's weight ± 5% for at least 3 last months and patient's agreement not to change food habits during the study
6. Menopausal women without or with HRT with a stable rate for at least 3 months
7. Able to understand and to give consent
8. Compliant with treatment

### Participant type(s)
Mixed

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
100

### Key exclusion criteria
1. Current cancer treatment
2. Diabetes
3. Severe intestinal problems
4. Autoimmune or chronic inflammatory diseases
5. Unintentional weight loss (> 10% of body weight) during the previous 6 months
6. Particular nutritional practice (vegetarians, vegans, high consumption of fiber)
7. Intake of food supplements
8. History of eating disorders (anorexia, bulimia)
9. Dieting at the time of inclusion
10. Underwent bariatric surgery
11. Consumption in the preceding 6 weeks of antibiotics or probiotics

12. Pregnancy, breastfeeding
13. Active smoker or ex-smoker for less than 2 years
14. Food allergy to one of the components of the supplement
15. Participation in another clinical study at the time of inclusion
16. Usually taking medication: anti-inflammatory drugs, corticosteroids, antiepileptics, neuroleptics, laxatives, antibiotics

### Date of first enrolment
01/10/2017

### Date of final enrolment
31/12/2018

## Locations

### Countries of recruitment
Belgium

### Study participating centre
**CHU UCL Namur Godinne**
Avenue du Dr Gaston Therasse 1
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## Sponsor information

### Organisation
KitoZyme

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### Sponsor type
Industry

### Website
http://kitozyme.com/

### ROR

https://ror.org/008a8ch32

# Funder(s)

**Funder type**
Other

**Funder Name**
Competitivity pole WAGRALIM (Public service of Wallonia region)

# Results and Publications

**Publication and dissemination plan**
Planned publication in a high-impact peer reviewed journal. Additional documents (study protocol, statistical analysis plan, informed consent form, clinical study report, analytic code) could be available for sharing with researchers or investigators beginning 3 months and ending 36 months following article publication (also after obtaining all participant's permission).

**Intention to publish date**
30/12/2019

**Individual participant data (IPD) sharing plan**
The ADIPOSTOP study represents a part of the multidisciplinary project containing several participants. Patient level data can be available only after obtaining data sharing permission from all the participants.

**IPD sharing plan summary**
Other