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Effects of three months ingestion of EBC extract (extract of an african plant) on body weight and adiposity.

Submission date
19/07/2013

Recruitment status
No longer recruiting

Registration date
23/04/2014

Overall study status
Completed

Last Edited
02/05/2014

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol
Background and study aims
Obesity is one of the most important health problems in Western countries. Strategies are needed to reduce body weight. This study will assess whether an EBC extract (African plant) works on the body weight and the lipid profile of obese or overweight people.

Who can participate?
Males and females between 20 and 55 without any documented cardiovascular problems and with a body mass index between 27.5 and 34.9 Kg/m2

What does the study involve?
Participants are randomly allocated to one of three groups: EBC extract 75 mg, EBC extract 150mg or a dummy extract (placebo). There is a first visit and 3 follow-up monthly visits.

What are the possible benefits and risks of participating?
The benefits of participating will be weight loss and no risks are expected.

Where is the study run from?
Hospital Clínic of Barcelona, Spain.

When is study starting and how long is it expected to run for?
The study started in May 2013 and is expected to run for a year.

Who is funding the study?
Biocentury (Spain).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
IRGA-01-2012

Study information

Scientific Title
Effects of three months ingestion of EBC extract on body weight and adiposity.

Study objectives
The benefit of the EBC extract will reduce at short term (3 months) body weight and fat body mass, as well as improve glucose metabolism parameters and lipid profile.

Ethics approval required
Old ethics approval format

Ethics approval(s)
This study has been approved by the Institutional Review Board of the Hospital Clínic of Barcelona.

Study design
Open randomized and double blind placebo-controlled clinical trial

Primary study design

Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Overweight and obesity

Interventions
Subjects are randomized to three groups:
Group 1: Receives 4 capsules/day of placebo
Group 2: Receives 4 capsules/day of 75 mg each of EBC extract
Group 3: Receives 4 capsules/day of 150 mg each of EBC extract

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
EBC extract

Primary outcome measure
1. Changes in body weight and body mass index
2. Changes in waist perimeter
3. Changes in fat body mass and distribution of fat in the body measured by DEXA (Dual-energy X-ray Absorptiometry)

Secondary outcome measures
1. Medical record:
A complete medical record will be obtained from all participants, which included data on alcohol intake, smoking and dietary habits. Blood pressure and heart rate will be measured with an electronic apparatus Omron HEM-705CP (Netherlands).
2. Nutrition assessment, and general analyses :
All participants will complete 7-day dietary register during the week previous to the physical and laboratory assessment. We will assess the total quantity of calories ingested in the previous week as well as the proportion corresponding to carbohydrates, lipids and proteins by using the Food Processor Nutrition & Fitness software (esha RESEARCH, Salem, OR, USA) . Overall nutrition will be determined by percentage of ideal weight, lean body mass and body mass index. Waist Perimeter will be measured. The proteic nutrition will be determined on the basis of

the following parameters: hemoglobin, total lymphocyte count, total proteins, albumin, prealbumin, transferrin and retinol-binding protein. Serum and intraerythrocytary folic acid concentrations will be measured, as well as serum vitamin A, B1, B12, C, E, B-carotenes, Zn, Mg and Se concentrations. Moreover, the following measurements will also be obtained: red blood cell count, hematocrit, mean corpuscular volume, leukocyte count, glucose, creatinine, electrolytes, uric acid, transaminases, lactate dehydrogenase, alkaline phosphatase, gammaglutamyl transpeptidase and bilirrubin. Physical activity will be measured using the Minnesota Leisure Time Physical Activity Questionnaire.
3. Plasma glucose and insulin concentration and Homeostasis Model Assessment (HOMA) will be determined.
4. Serum lipoproteins and others:
Total cholesterol, triglycerides, cHDL, cLDL, Apo A1, Apo B, and lipoprotein (a) will be determined.
5. Diet and exercise monitoring:
All participants will follow an isocaloric diet prepared according to their personal preferences. The diet will be strictly monitored during the study. Diet compliance will be assessed from 7-days diet records administered before each evaluation. This assessment will be administered by trained personnel. The foods ingested will be converted into nutritional values with the aid of the Professional Diet Balancer software (Cardinal Health Systems, Inc., Edina, MN). Physical activity will also be evaluated with the Minnesota Leisure Time Physical Activity questionnaire which has also been validated in Spain. Control of the diet and physical exercise will be carried out before and after each intervention, the same day on which the clinical examinations are performed and blood is withdrawn for immunologic studies.

Overall study start date
19/05/2013

Completion date
19/05/2014

Eligibility

Key inclusion criteria
Males and females between 20 and 55 years old without documented cardiovascular disease (ischemic heart disease angina or recent or old myocardial infarction or previous or cerebral vascular accident, peripheral vascular disease) and who have a body mass index between 27.5 and 34.9 Kg/m2.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
120 participants (60 men and 60 women)

Key exclusion criteria

Subjects with a previous history of cardiovascular disease (ischemic heart disease angina or recent or old myocardial infarction, cerebral vascular accident, or peripheral vascular disease), any severe chronic disease, alcoholism or other toxic abuse will be excluded, as well as those subjects who had taken drugs or followed dietary interventions with potential effects on body weight in the last three months. Subjects who had changed their weight +/-3 kg in the last 3 months were also excluded from the study.

Date of first enrolment
19/05/2013

Date of final enrolment
19/05/2014

Locations

Countries of recruitment
Spain

Study participating centre
Hospital CLínic de Barcelona
Barcelona
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08036

Sponsor information

Organisation
Biocentury SLU (Spain)

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Sponsor type
Industry

ROR
https://ror.org/02tx52885

Funder(s)

Funder type
Industry

Funder Name
Biocentury SLU (Spain)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration