

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	☐ Prospectively registered
		☐ Protocol
Registration date 23/04/2014	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 02/05/2014	Condition category Nutritional, Metabolic, Endocrine	☐ 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**Protocol serial number**

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

Study type(s)

Treatment

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(s)

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)

Key secondary outcome(s))

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 bilirubin. 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.

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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
Spain
08036

Sponsor information

Organisation
Biocentury SLU (Spain)

ROR
<https://ror.org/02tx52885>

Funder(s)

Funder type
Industry

Funder Name
Biocentury SLU (Spain)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration