

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

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| <b>Submission date</b><br>19/07/2013   | <b>Recruitment status</b><br>No longer recruiting              | <input type="checkbox"/> Prospectively registered    |
|  |  | <input type="checkbox"/> Protocol                    |
| <b>Registration date</b><br>23/04/2014 | <b>Overall study status</b><br>Completed                       | <input type="checkbox"/> Statistical analysis plan   |
|  |  | <input type="checkbox"/> Results                     |
| <b>Last Edited</b><br>02/05/2014       | <b>Condition category</b><br>Nutritional, Metabolic, Endocrine | <input type="checkbox"/> Individual participant data |
|  |  | <input type="checkbox"/> 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/m<sup>2</sup>

### 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?

Dr. Ramon Estruch  
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## Contact information

**Type(s)**

Scientific

**Contact name**

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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 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.

#### **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/m<sup>2</sup>.

#### **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

Spain

08036

## **Sponsor information**

**Organisation**

Biocentury SLU (Spain)

**Sponsor details**

Ctra. N-II km 71417242 Quart

Girona

Spain

17458

**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