

# Confirmatory study of the effectiveness of a vegetal extract (EBC) on body weight and adiposity

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 27/04/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 27/02/2019	<b>Condition category</b> 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 a medical term used to describe someone who is very overweight. It is generally caused by eating too much and doing too little exercise. Being obese can lead to a number of serious and potentially life-changing conditions including type 2 diabetes, coronary heart disease, some cancers (e.g. breast and bowel cancers) and stroke. It can also affect a person's mental well-being, leading to low self-esteem and depression. This study looks at whether an EBC extract (vegetal extract) effects a person's body weight, fat in the body and glucose metabolism of obese or overweight people.

### Who can participate?

Adults aged 20 and 55 without any known cardiovascular (for example, heart) 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 two main groups. Those in group 1 are given 4 capsules of EBC extract to take a day. Those in group 2 are given 4 capsules of a placebo (dummy pill) to take a day. All participants in both groups are assessed for changes in body weight, BMI and body fat at the start of the study and at set periods throughout until the final assessment at 6 months.

### 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?

October 2015 to December 2016

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**  
N/A

## Study information

**Scientific Title**  
Confirmatory study of the effectiveness of a vegetal extract (EBC) on body weight and adiposity: a randomised controlled trial

**Study objectives**  
The benefit of the EBC extract will reduce at medium-term (6 months) body weight and fat body mass, as well as improve other parameters of adiposity in both men and women (fertile and postmenopausal).

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**

**Study design**

Randomised controlled trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet****Health condition(s) or problem(s) studied**

Overweight and obesity

**Interventions**

Subjects are randomized to six groups:

Group 1: Menopausal women who receive 4 capsules/day of placebo

Group 2: Menopausal women who receive 4 capsules/day of 150 mg each of EBC extract

Group 3: Fertile women who receive 4 capsules/day of placebo

Group 4: Menopausal women who receive 4 capsules/day of 150 mg each of EBC extract

Group 5: Men who receive 4 capsules/day of placebo

Group 6: Men who receive 4 capsules/day of 150 mg each of EBC extract

**Intervention Type**

Supplement

**Primary outcome measure**

1. Changes in body weight measured using a weigh scale, Roman type, Brand Atlantis with an accuracy of 100 grams, at baseline, 1, 2, 3, 4, 5 and 6 months after intervention
2. Changes in body mass index measured applying the Quetelet index ( $\text{weight}/(\text{height})^2$ ), at baseline, 1, 2, 3, 4, 5 and 6 months after intervention
3. Changes in waist perimeter measured using a SECA201 (CBA04) measuring tape, at baseline, 1, 2, 3, 4, 5 and 6 months after intervention
4. Changes in fat body mass and distribution of fat in the body measured by DEXA (Dual-energy X-ray Absorptiometry), at baseline, 3 and 6 months after intervention

**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, at baseline, 3 and 6 months
2. Blood pressure and heart rate will be measured with an electronic apparatus Omron HEM-705CP (Netherlands), at baseline, 3 and 6 months after intervention
3. Nutrition assessment, and general analyses:
  - 3.1. Data collected as part of a 7 day dietary register, including total quantity of calories and

proportion corresponding to carbohydrates, lipids and proteins, assessed by Food Processor Nutrition & Fitness software during the week previous to the physical and laboratory assessment, at baseline, 1, 2, 3, 4, 5 and 6 months after intervention

3.2. Protein nutrition, determined on the basis of the following parameters: hemoglobin, total lymphocyte count, total proteins, albumin, prealbumin, transferrin and retinol-binding protein, measured in central laboratory, at baseline, 3 and 6 months after intervention

3.3. Serum and intraerythrocytary folic acid concentrations, serum vitamin A, B1, B12, C, E, Zn and Mg concentrations, measured in central laboratory, at baseline, 3 and 6 months after intervention

3.4. Red blood cell count, hematocrit, mean corpuscular volume, leukocyte count, glucose, creatinine, electrolytes, uric acid, transaminases, lactate dehydrogenase, alkaline phosphatase, gammaglutamyl transpeptidase and bilirubin, measured in central laboratory, at baseline, 3 and 6 months after intervention

3.5. Physical activity will be measured using the Minnesota Leisure Time Physical Activity Questionnaire, which has also been validated in Spain, at baseline, 3 and 6 months after intervention

4. Plasma glucose and insulin concentration and Homeostasis Model Assessment (HOMA) will be determined by the glucose oxidase method, at baseline, 3 and 6 months after intervention

5. Serum lipoproteins and others: Total cholesterol and triglycerides are determined by enzymatic methods, HDL cholesterol will be measured after precipitation with phosphotungstic acid and enzymatic method, and LDL cholesterol from the Friedewald formula [ $LDL-C = TC - (HDL + Triglycerides / 5)$ ], at baseline, 3 and 6 months after intervention. Apo A1, Apo B, and lipoprotein (a) will be determined in central laboratory, at baseline, 3 and 6 months after intervention

6. 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

#### **Overall study start date**

01/10/2015

#### **Completion date**

30/12/2016

## **Eligibility**

#### **Key inclusion criteria**

1. Males and females (50% menopausal and 50% fertile)
2. Aged between 20 and 55 years old
3. No documented cardiovascular disease (ischemic heart disease, angina or recent or old myocardial infarction or previous or cerebral vascular accident, peripheral vascular disease)
4. Body mass index between 27.5 and 34.9 Kg/m<sup>2</sup>

#### **Participant type(s)**

Healthy volunteer

#### **Age group**

Adult

#### **Sex**

Both

**Target number of participants**

120 participants (40 men and 80 women)

**Key exclusion criteria**

1. Previous history of cardiovascular disease (ischemic heart disease angina or recent or old myocardial infarction, cerebral vascular accident, or peripheral vascular disease)
2. Any severe chronic disease, alcoholism or other toxic abuse
3. Subjects who had taken drugs or followed dietary interventions with potential effects on body weight in the last 3 months
4. Subjects who had changed their weight +/-3 kg in the last 3 months

**Date of first enrolment**

02/11/2015

**Date of final enrolment**

06/06/2016

**Locations****Countries of recruitment**

Spain

**Study participating centre**

Hospital Clínic de Barcelona

Barcelona

Spain

08036

**Sponsor information****Organisation**

Biocentury SLU

**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

## **Results and Publications**

### **Publication and dissemination plan**

Not provided at time of registration

### **Intention to publish date**

30/12/2017

### **Individual participant data (IPD) sharing plan**

### **IPD sharing plan summary**

Not expected to be made available