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

Submission date
01/04/2016

Recruitment status
No longer recruiting

Registration date
27/04/2016

Overall study status
Completed

Last Edited
27/02/2019

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 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?
Adult s 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/m2.

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?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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)
Institutional Review Board of the University of Barcelona, 18/05/2015, ref: IRB00003099

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

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(s)
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 (weight/(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

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, at abseline, 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 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 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 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 bilirrubin, measured in central laboratory, at baseline, 3 and 6 months after intervention 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

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/m2

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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

ROR
https://ror.org/02tx52885

Funder(s)

Funder type
Industry

Funder Name
Biocentury SLU

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available