

# Risks and benefits of moderate beer intake (with and without alcohol) on osteoporosis in postmenopausal women

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| <b>Submission date</b><br>13/11/2017   | <b>Recruitment status</b><br>No longer recruiting     | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>02/01/2018 | <b>Overall study status</b><br>Completed              | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>05/07/2023       | <b>Condition category</b><br>Musculoskeletal Diseases | <input type="checkbox"/> Individual participant data  |

## Plain English summary of protocol

### Background and study aims

Hip fractures are a major public health problem worldwide, contributing to decrease quality of life and premature death. More than two-thirds of all hip fractures occur in women due to postmenopausal osteoporosis (bone loss that occurs after menopause due to changes in hormone levels). To improve nutrition and lifestyle habits, as well as to increase physical activity are the best weapons to reduce the incidence of osteoporosis (and hip fractures). The aim of this study is to evaluate the beneficial effects of moderate beer intake (regular beer and dealcoholized beer) on bone mineral density (BMD) in postmenopausal women.

### Who can participate?

Women aged 45 to 70 years old.

### What does the study involve?

Participants are allocated to one of three groups. Those in the first group drink water for two years at dinner. Those in the second group receive dealcoholized beer for two years. Those in the last group receive regular beer (330 mL/day) for two years. In order to know whether beer components (e.g. ethanol, silicon, polyphenols) promote bone formation and/or reduce bone resorption this study will investigate the rates of bone formation and bone loss by measuring their biomarkers in serum and urine at baseline and at six, 12 and 24 months.

### What are the possible benefits and risks of participating?

As we explained before, it has been suggested that moderate beer intake may have a protective role in osteoporosis, by increasing bone formation or decreasing bone resorption by several mechanisms. This study will allow to analyse bone mineral density and other mechanisms by which beer or dealcoholised beer may prevent bone loss and increase bone formation, reducing medication and improving live quality. There are no risks to participate in this study as long as the exclusion criteria are followed. The study was conducted according to the Declaration of Helsinki of the World Medical Association.

Where is the study run from?  
Hospital Clínic of Barcelona (IDIBAPS) (Spain)

When is the study starting and how long is it expected to run for?  
January 2017 to August 2021

Who is funding the study?  
CIBER (Consortio Centro de Investigación Biomédica en Red, M.P) (Spain)

Who is the main contact?  
Dr Rosa María Lamuela-Raventós (Scientific)

## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

**Protocol serial number**  
IRB00003099

## Study information

**Scientific Title**  
Effects of prenylflavonoids of beer and dealcoholised beer on bone mineral density and molecular bone markers

**Acronym**  
POLYBOST

**Study objectives**

Due to its polyphenol, silicon and ethanol content, moderate beer consumption may participate to prevent osteoporosis in postmenopausal women, providing beneficial effects on bone tissue, stimulating human osteoblasts formation, reducing bone fragility and increasing bone mineral density (BMD).

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Institutional Review Board of the University of Barcelona, 09/03/2017

### **Study design**

A long-term (2 years) parallel-group controlled open intervention trial

### **Primary study design**

Interventional

### **Study type(s)**

Prevention

### **Health condition(s) or problem(s) studied**

Bone Mineral Density (BMD)

### **Interventions**

Current intervention as of 20/05/2022:

Participants are assigned to the following intervention groups:

Intervention 1: Control group with water for 2 years (ERB-C).

Intervention 2: 660 mL/day of dealcoholised beer for 2 years (ERB-D).

Intervention 3: 330 mL/day (15 g of ethanol/day) of regular beer for 2 years (ERB-A).

After a run-in period of 15 days, in which subjects are asked not to consume any alcoholic beverage or alcohol-free beer, they receive 15 g of ethanol/day as regular beer, the same amount of nonalcoholic components (polyphenols and silicon) in alcohol-free beer and the same amount of water at dinner during two years in a prospective parallel and controlled trial. The follow-up for all interventions is at baseline, six months, 12 months and 24 months. The compliance of interventions are assessed by data from questionnaires and by determination of isoxanthohumol levels in urine, a biomarker of beer intake.

Previous intervention:

Participants are randomly assigned following simple randomisation procedures (computerised random numbers) to 1 of 3 intervention groups.

Intervention 1: Control group with water for 2 years (ERB-C).

Intervention 2: 660 mL/day of dealcoholised beer for 2 years (ERB-D).

Intervention 3: 330 mL/day (15 g of ethanol/day) of regular beer for 2 years (ERB-A).

After a run-in period of 30 days, in which subjects are asked not to consume any alcoholic beverage or alcohol-free beer, they receive 15 g of ethanol/day as regular beer, the same amount of nonalcoholic components (polyphenols and silicon) in alcohol-free beer and the same amount of water at dinner during two years in a prospective, randomized, parallel and controlled

trial. The follow-up for all interventions is at baseline, six months, 12 months and 24 months. The compliance of interventions are assessed by data from questionnaires and by determination of isoxanthohumol levels in urine, a biomarker of beer intake.

## **Intervention Type**

Other

## **Primary outcome(s)**

1. Bone mineral density is measured using the dual energy X-ray absorptiometry (DXA) at baseline, 1 year and at the end of the intervention period
2. Trabecular bone score (TBS) at lumbar spine is measured using the DXA at baseline, 1 year and at the end of the intervention period
3. Volumetric dual-energy X-ray absorptiometry (3D-DXA) at the proximal femur is measured using 3D-DXA at baseline, 1 year and at the end of the intervention period
4. Markers of bone formation (serum PINP and bone AP concentrations) and bone resorption (s-CTX and u-NTX concentrations) are measured by ELISA and electrochemiluminescence, CrossLaps ELISA and ELISA Ostex, respectively, at baseline, 6 months, 1 year and at the end of the intervention period
5. Molecular mediators of bone turnover, namely sclerostin and Dkk-1 are measured using a newly developed ELISA (Biochemical GMBH) at baseline, 6 months, 1 year and at the end of the intervention period

## **Key secondary outcome(s)**

1. At the beginning, 6 months, 1 year and at the end of each intervention period a medical assessment will be performed which included: clinical history (personal questionnaire), anthropometric measurements (measured using stand-alone stadiometer and a tape measure), clinical blood pressure (measured using and electronic pressure Omron apparatus) and full blood analysis (glucose, glycated hemoglobin, triglycerids, total cholesterol, HDLc, LDLc, lipoprotein (a), creatinine, calcium, phosphatase, PTH, 25OHD measured using blood samples) and the collection of 24-h urine samples
2. Dietary evaluation: nutrient intake and adherence to dietary recommendations is measured using a 7-day food record validated nutritional questionnaire and a Food Frequency test at baseline, six months, one year and at the end of the interventions
3. Physical activity is measured using the Minnesota Leisure Time Physical Activity questionnaire at baseline, six months, one year and at the end of the intervention period
4. Bioavailability, identification and quantification polyphenols in biological samples is measured using LTQ-Orbitrap Mass Spectrometry and HPLC-MS/MS at baseline and at the end of the intervention period
5. Changes in urine metabolites is measured using mass spectrometry and statistical analysis at baseline and at the end of the intervention period

## **Completion date**

31/08/2021

## **Eligibility**

### **Key inclusion criteria**

Current participant inclusion criteria as of 20/05/2022:

1. Postmenopausal women between 45 and 70 years of age

2. FSH 23-116 U/l
3. Estradiol (E2) <37 pg/ml
4. Amenorrhea  $\geq$ 12 months

Previous participant inclusion criteria:

1. Women between 45 and 70 years of age within 5 years of menopause
2. FSH > 3 Miu/mL
3. Estradiol (E2) = 30 pg/mL
4. Amenorrhea  $\geq$  12 months

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

Healthy volunteer

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Sex**

Female

### **Total final enrolment**

37

### **Key exclusion criteria**

Current participant exclusion criteria as of 08/08/2022:

1. Patients with known diseases affecting bone metabolism (rheumatoid arthritis, hyperthyroidism, hypercortisolism, renal bone disease, chronic liver disease, among others)
2. Use of drugs affecting bone metabolism (fluorides, bisphosphonates, calcitonin, teriparatide or parathormone, strontium ranelate, SERMs, estrogen therapy, anabolic steroids, chronic glucocorticoids (>3 months), cytostatics, antiandrogens, and antiepileptics)
3. Participants who received silicon or polyphenol supplements

Previous participant exclusion criteria as of 20/05/2022:

1. Patients with known diseases affecting bone metabolism (rheumatoid arthritis, hyperthyroidism, hypercortisolism, renal bone disease, chronic liver disease, among others)
2. Participants who received silicon or polyphenol supplements

Previous participant exclusion criteria:

1. Patients with known diseases affecting bone metabolism (rheumatoid arthritis, hyperthyroidism, surgical menopause, hypercortisolism, renal bone disease, chronic liver disease, among others)
2. Use of drugs affecting bone metabolism (fluorides, bisphosphonates, calcitonin, teriparatide or parathormone, strontium ranelate, SERMs, estrogen therapy, anabolic steroids, chronic glucocorticoids (> 3 months), cytostatics, antiandrogens and antiepileptics)
3. Participants who received silicon or polyphenol supplements

### **Date of first enrolment**

01/04/2017

**Date of final enrolment**

31/07/2019

## Locations

**Countries of recruitment**

Spain

**Study participating centre**

Hospital Clínic of Barcelona (IDIBAPS)

Villaroel 170

Barcelona

Spain

08036

## Sponsor information

**Organisation**

CIBER (Consorcio Centro de Investigación Biomédica en Red, M.P.)

**ROR**

<https://ror.org/00dwgct76>

## Funder(s)

**Funder type**

Research organisation

**Funder Name**

European Research Advisory Board (ERAB): The European Foundation for Alcohol Research

## Results and Publications

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

At this moment, our participant-level data is not expected to be available, there isn't enough information. As researchers, we are responsible to share the data generated by our interventional clinical trial. Following the ethical obligation, we could share individual participant data that underlie the results reported in an article as soon as the article would be written to an end date to investigators or researchers who want to provide new proposals. All personal data will be protected.

## IPD sharing plan summary

Not expected to be made available

### Study outputs

| Output type                                   | Details                         | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---------------------------------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a>               | Effect on cardiovascular health | 15/11/2022   | 06/04/2023 | Yes            | No              |
| <a href="#">Results article</a>               |                                 | 04/07/2023   | 05/07/2023 | Yes            | No              |
| <a href="#">Participant information sheet</a> | Participant information sheet   | 11/11/2025   | 11/11/2025 | No             | Yes             |