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

Submission date
13/11/2017

Recruitment status
No longer recruiting

Registration date
02/01/2018

Overall study status
Completed

Last Edited
05/07/2023

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 (Consorcio Centro de Investigación Biomédica en Red, M.P) (Spain)

Who is the main contact?
Dr Rosa MaríaLamuela-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 electrochemiluminiscence, 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 ≥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 ≥ 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
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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?
Results article		15/11/2022	06/04/2023	Yes	No
Results article	Effect on cardiovascular health	04/07/2023	05/07/2023	Yes	No