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Evaluation of moderate daily intake of beer in reducing menopausal symptoms: estrogenic effect of hop prenylflavanoids

Submission date	Recruitment status	[_] Prospectively registered
13/11/2017	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
23/01/2018	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
24/02/2023	Other	

Plain English summary of protocol

Background and study aims
The menopause is a natural part of ageing that usually occurs between 45 and 55 years of age as a woman's estrogen levels decline, which triggers the uncomfortable symptoms of hot flushes, night sweats, sleep disturbances, and vaginal dryness. These symptoms can significantly affect the quality of life of menopausal women. Phytoestrogens are compounds naturally found in some vegetables which act like estrogen - the most popular ones are soy and flax-seed phytoestrogens. Hops used in beer brewing are a rich source of phytoestrogens, and moderate daily intake of beer may decrease menopausal symptoms. Therefore, this study aims to find out whether moderate daily intake of beer reduces menopausal discomforts.

Who can participate?
Postmenopausal women aged between 45 and 70

What does the study involve?
Participants are assigned to one of the three study groups according to their preference due to the complexity of the mid-term alcohol intake of the intervention. The first group drink water, the second group drink beer without alcohol, and the third group drink regular beer every day for 6 months. At the beginning and at the end of each intervention period a medical assessment is performed which includes the participant’s clinical history, dietary evaluation, body measurements, blood pressure, and the collection of blood and urine samples.

What are the possible benefits and risks of participating?
Daily intake of beer may improve menopausal symptoms. There are no risks of participating in this study.

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 January 2020

Who is funding the study?
European Research Advisory Board (ERAB): The European Foundation for Alcohol Research

Who is the main contact?
Dr Rosa M Lamuela-Raventos

Contact information

Type(s)
Scientific

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Protocol serial number
IRB00003099

Study information

Scientific Title
Effects of prenylflavonoids of beer and dealcoholised beer on menopausal symptoms and estrogens

Acronym
POLYBHOR

Study objectives
Current study hypothesis as of 11/05/2021:
Due to its phytoestrogen content, moderate beer consumption reduces menopausal symptoms and changes menopausal-related hormonal profile.

Previous study hypothesis:
Due to its phytoestrogen content, moderate beer consumption reduces menopausal symptoms and improves menopausal-related hormones.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Review Board of the University of Barcelona, 09/03/2017

Study design
Mid-term (6 months) non-randomized parallel-group controlled open intervention trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Menopause

Interventions
Current interventions as of 11/05/2021:
All participants in the study are clinically examined and sign an informed consent to accept their participation in the study. Participants were assigned to one of the three study groups according to their preference due to the complexity of the mid-term alcohol intake of the intervention.

Intervention 1: control group with water for 6 months (ERB-C)
Intervention 2: 660 mL/day of dealcoholised beer for 6 months (ERB-D)
Intervention 3: 330 mL/day (15 g of ethanol/day) of regular beer for 6 months (ERB-A)

At the beginning and at the end of each intervention period a medical assessment will be performed which included: clinical history, dietary evaluation, anthropometric measurements, clinical blood pressure and full blood analysis (glucose, glycated hemoglobin, triglycerides, total cholesterol, HDLc, LDLc, lipoprotein (a), creatinine, calcium, phosphatase, PTH, 25OHD) and the collection of 24-h urine samples.

Previous interventions:
All participants in the study are clinically examined and sign an informed consent to accept their participation in the study. Participants are randomly assigned following simple randomisation procedures (computerised random numbers) to 1 of 3 intervention groups.

Intervention 1: control group with water for 6 months (ERB-C)
Intervention 2: 660 ml/day of dealcoholised beer for 6 months (ERB-D)
Intervention 3: 330 ml/day (15 g of ethanol/day) of regular beer for 6 months (ERB-A)

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, dietary evaluation, anthropometric measurements, clinical blood pressure and full blood analysis (glucose, glycated hemoglobin, triglycerides, total cholesterol, HDLc, LDLc, lipoprotein (a), creatinine, calcium, phosphatase, PTH, 25OHD) and the collection of 24-h urine samples.

Intervention Type
Other

Primary outcome(s)

1. Menopausal symptoms (hot flashes, sweating, palpitations, dizziness, vaginal dryness, mood swings, etc), measured using the Menopause Rating Scale at baseline, 1.5, 3 and 6 months
2. Calcium excretion, measured using liquid chromatography coupled mass spectrometry at baseline and 6 months
3. Menopausal-related hormone profile, measured using ELISA at baseline, 1.5, 3 and 6 months

Key secondary outcome(s))
Current secondary outcome measures as of 11/05/2021:
1. Dietary evaluation: nutrient intake and adherence to the dietary recommendations measured using a 7-day food record validated nutritional questionnaire at the baseline and at 6 months. In addition, the food frequency questionnaire and 14-point Mediterranean Diet Adherence questionnaire are recorded at baseline.
2. Physical activity is measured using the Minnesota Leisure Time Physical Activity questionnaire at baseline and 6 months
3. Bioavailability, identification and quantification of 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
4. Changes in urine metabolites are measured using mass spectrometry and statistical analysis at baseline and at the end of the intervention period

Previous secondary outcome measures:
1. Dietary evaluation: nutrient intake and adherence to the dietary recommendations are measured using a 7-day food record validated nutritional questionnaire and a Food Frequency Test at the baseline, 6 months, 1 year and 2 years
2. Physical activity is measured using the Minnesota Leisure Time Physical Activity questionnaire at baseline, 6 months, 1 year and 2 years
3. Bioavailability, identification and quantification of 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
4. Changes in urine metabolites are measured using mass spectrometry and statistical analysis at baseline and at the end of the intervention period

Completion date
30/01/2020

Eligibility

Key inclusion criteria
Current inclusion criteria as of 11/05/2021:
Postmenopausal women between 45 and 70 years of age:
1. FSH 23-116 U/L
2. Estradiol (E2) <37 pg/ml
3. Amenorrhea ≥12 months

Previous inclusion criteria:
Women between 45 and 70 years of age within 5 years of menopause:
1. FSH >3 Miu/ml
2. Estradiol (E2) =30 pg/ml
3. 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 exclusion criteria as of 28/05/2021:
1. Participants using estrogen therapy
2. Participants who received silicon or polyphenol supplements

Previous 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
30/06/2019

Locations

Countries of recruitment
Spain

Study participating centre
Hospital Clínic of Barcelona (IDIBAPS)
Villaroel 170
Barcelona
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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
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Rosa M. Lamuela Raventós.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		30/06/2021	24/02/2023	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes