

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

Submission date 13/11/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 23/01/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 24/02/2023	Condition category Other	<input type="checkbox"/> Individual participant data

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

Contact name

Dr Rosa María Lamuela-Raventós

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08028

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Non randomised study

Study setting(s)

Hospital

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

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 measure

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

Secondary outcome measures

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

Overall study start date

02/01/2017

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 \geq 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 \geq 12 months

Participant type(s)

Healthy volunteer

Age group

Adult

Sex

Female

Target number of participants

60

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

Spain

08036

Sponsor information

Organisation

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

Sponsor details

C/Monforte de Lemos, 3-5. Pabellón 11. Planta 0

Madrid

Spain

28029

Sponsor type

Research organisation

Website

<http://www.ciberobn.es>

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

Publication and dissemination plan

Current publication and dissemination plan, as of 14/12/2021:

During the recruitment period, the trialists have written a review about polyphenols and menopausal symptoms, "Beer polyphenols and menopause: effects and mechanisms – A review of current knowledge" (Oxidative Medicine and Cellular Longevity, 2017). After this period, they have published a second publication titled "Moderate consumption of beer (with and without ethanol) and menopausal symptoms: results from a parallel clinical trial in postmenopausal women" (Nutrients, 2021) <https://doi.org/10.3390/nu13072278>

Previous publication and dissemination plan as of 11/05/2021:

During the recruitment period, the trialists have written a review about polyphenols and menopausal symptoms, "Beer polyphenols and menopause: effects and mechanisms – A review of current knowledge" (Oxidative Medicine and Cellular Longevity, 2017). After this period, they plan to publish a second publication in a high-impact Journal about "Moderate daily beer (with and without ethanol) consumption and menopausal symptoms: results from a parallel clinical trial in postmenopausal women". It would be submitted by June 2021.

Previous publication and dissemination plan:

During the recruitment period, the trialists have written a review about polyphenols and menopausal symptoms, "Beer polyphenols and menopause: effects and mechanisms – A review of current knowledge" (Oxidative Medicine and Cellular Longevity, 2017). After this period, they plan to publish a second publication in a high-impact Journal about "Moderate beer consumption and menopausal symptoms: results from a randomized clinical trial in postmenopausal women". It would be submitted by June 2018.

Intention to publish date

01/06/2021

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