

Prenylflavanoids as a biomarker of beer consumption

Submission date 24/04/2013	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 16/05/2013	Overall study status Completed	☐ Statistical analysis plan
		☒ Results
Last Edited 23/05/2014	Condition category Nutritional, Metabolic, Endocrine	☐ Individual participant data

Plain English summary of protocol

Background and study aims

Prenylflavanoids (a group of plant hormones) are mainly found in hops, and therefore, in beer. Thus, the intake of beer might be assessed through its quantity present in the urine. The aim of this study is to assess the usefulness of urinary prenylflavanoids as a biomarker of beer consumption.

Who can participate?

Healthy adults, in the age range 18-35 years, non-smokers, without previous history of heart, liver or kidney disease, disorders with body balance, any other long-lasting diseases, high blood pressure or Dyslipidemia (abnormal cholesterol/fat level in the blood), alcoholism or other toxic abuse.

What does the study involve?

The volunteers were given different doses of beer at dinner in a random order. Male volunteers consumed 330, 660 and 990 ml of beer, and female volunteers consumed 330, 495 and 660 ml of beer. Before each dose, volunteers followed a 4-day wash-out period in which they were requested to avoid consuming any type of hop-based products and beer. Urine sample was collected before each dose.

What are the possible benefits and risks of participating?

There are no risks as long as the exclusion criteria are followed. The study was conducted according to the Declaration of Helsinki of the World Medical Association. The study was explained to subjects through verbal and written instructions, and written informed consent was obtained before participation.

Where is the study run from?

This study involved the Department of Nutrition and Food Science of the University of Barcelona (Barcelona, Spain) and the Department of Internal Medicine, Hospital Clinic, Institut d'Investigació Biomèdica August Pi i Sunyer (IDIBAPS), University of Barcelona (Barcelona, Spain).

When is the study starting and how long is it expected to run for?

This study was conducted between March 2011 and October 2011.

Who is funding the study?

This study was supported by the European Foundation for Alcohol Research (ERAB) (Belgium).

Who is the main contact?

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Contact information

Type(s)

Scientific

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Additional identifiers

Study information

Scientific Title

Urinary isoxanthohumol excretion as a biomarker of beer consumption

Study objectives

Hops and beer are a unique source of xanthohumol, isoxanthohumol and 8-prenylrningenin. Therefore, prenylflavanoids, such as isoxanthohumol and their metabolites may be a potent biomarker of beer consumption, thus the intake of beer can be assessed by quantifying isoxanthohumol in urine.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of University of Barcelona (Institutional Review Board IRB00003099), 04/07 /2011

Primary study design

Interventional

Study design

Dose-response randomised cross-over clinical trial

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied

Beer consumption

Interventions

Male volunteers:

Intervention 1: Administration of 330 mL beer (14.5 g ethanol)

Intervention 2: Administration of 660 mL beer (29 g ethanol)

Intervention 3: Administration of 990 mL beer (43.5 g ethanol)

Female volunteers:

Intervention 1: Administration of 330 mL beer (14.5 g ethanol)

Intervention 2: Administration of 495 mL beer (21.7 g ethanol)

Intervention 3: Administration of 660 mL beer (29 g ethanol)

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Concentrations of urinary prenylflavanoids will be determined by liquid chromatography coupled to tandem mass spectrometry (LCMS/MS). These determinations will be carried out in first morning urine samples collected the day before the first intervention and in the subsequent mornings following each intervention. Creatinine adjustment will be used to normalize analyte concentrations in these urine samples.

Key secondary outcome(s)

No secondary outcome measures

Completion date

28/10/2011

Eligibility**Key inclusion criteria**

Young healthy volunteers of age 28 ± 3 years, body mass index 22.69 ± 2.69 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 criteria - angina, recent or old myocardial infarction, cerebral vascular accident or peripheral vascular disease)
2. Homeostatic disorders
3. Any several chronic diseases
4. Hypertension or dyslipidemia
5. Smoking subjects
6. Alcoholism
7. Other toxic abuse

Date of first enrolment

31/03/2011

Date of final enrolment

28/10/2011

Locations**Countries of recruitment**

Spain

Study participating centre

Av. Joan XXII s/n

Barcelona

Spain

08028

Sponsor information**Organisation**

Center for Biomedical Research in Pathophysiology of Obesity & Nutrition (Ciber Fisiopatología de la Obesidad Nutrición)(Spain)

ROR

<https://ror.org/02s65tk16>

Funder(s)

Funder type

Research organisation

Funder Name

Center for Biomedical Research in Pathophysiology of Obesity and Nutrition (CIBERObn) (Spain)

Results and Publications

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

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2014		Yes	No