

Urinary tartaric acid as a sensitive dietary biomarker of moderate wine consumption

Submission date 22/04/2013	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 09/05/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 03/06/2014	Condition category Other	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Tartaric acid is one of the most abundant acids in red and white wines. Intake of wine might be assessed through urinary concentration. The aim of this study is to assess the usefulness of urinary tartaric acid as a biomarker of wine consumption.

Who can participate?

Healthy adults (males), in the age range 18-50 years, non-smokers, without previous history of cardiovascular disease, hepatic or renal disease, homeostatic disorders, any several chronic diseases, hypertension or dislipemia, alcoholism or other toxic abuse.

What does the study involve?

The interventions consisted of intake at dinner, in a random order, of 100, 200 and 300 ml of red wine, corresponding to 10.3, 20.5 and 30.8 g of ethanol, respectively. Before each wine consumption participants followed a 7-day wash-out period during which they were requested to avoid consuming grape-based products. First morning urines were collected the day before the first intervention and in the morning following each intervention.

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?
Between July 2012 and July 2013.

Who is funding the study?
This study is supported by a research grant from Junta de Andalucía (Spain).

Who is the main contact
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Use of urinary concentration of tartaric acid as a dietary biomarker of red and white wine: an open randomized cross-over controlled trial

Study objectives
Tartaric acid is one of the most abundant acids in red and white wines. In nature, it is mainly specific to grapes, and therefore, also to wine. Thus, intake of wine might be assessed through its urinary concentration.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of Clinical Investigation of the University of Barcelona (Spain), 05/02/2013, ref: IRB0003099

Study design

Open randomized cross-over controlled clinical trial with three feeding interventions

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Screening

Participant information sheet

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

Health condition(s) or problem(s) studied

Concentration of tartaric acid in urine

Interventions

Intervention 1: Administration of 100 ml red wine (10.3 g ethanol).

Intervention 2: Administration of 200 ml red wine (20.5 g ethanol).

Intervention 3: Administration of 300 ml red wine (30.8 g ethanol).

Before each intervention, participants followed a 7-day washout period, avoiding consuming grape products.

Each subject consumed three doses of red wine (100, 200 and 300 ml) in a random order at three different times, separated by 7-day wash-out periods. Each intervention consisted of a single dose of one of these volumes (100, 200 or 300 ml) and the total duration of the study was 22 days (i.e. 7-day wash-out >first intervention on day 7 >7-day wash-out >second intervention on day 14 >7-day wash-out >third intervention on day 21>end of study).

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Concentrations of urinary tartaric acid will be determined by liquid chromatography coupled to tandem mass spectrometry (LCMS/MS). These determinations will be carried out in first morning

urines collected the day before the first intervention and in the morning following each intervention. Creatinine adjustment was used to normalize analyze concentrations in these urine samples.

Urinary concentration of tartaric acid was measured at day 7 (before first intervention), at day 8 (10 hours after first intervention), at day 14 (before second intervention), at day 15 (10 hours after second intervention), at day 21 (before third intervention) and at day 22 (10 hours after third intervention).

Secondary outcome measures

No secondary outcome measures

Overall study start date

01/07/2012

Completion date

01/07/2013

Eligibility

Key inclusion criteria

Healthy adults, males, 18-50 years

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

50 Years

Sex

Male

Target number of participants

21

Key exclusion criteria

1. Previous history of cardiovascular disease (ischemic heart disease - angina or recent or old myocardial infarction, cerebral vascular accident, or peripheral vascular disease)
2. Homeostatic disorders
3. Any several chronic diseases
4. Hypertension or dislipemia
5. Smoking subjects
6. Alcoholism
7. Other toxic abuse

Date of first enrolment

01/07/2012

Date of final enrolment

01/07/2013

Locations

Countries of recruitment

Spain

Study participating centre

Food Science Department

Barcelona

Spain

08028

Sponsor information

Organisation

CIBER Pathophysiology of Obesity and Nutrition [Ciber Fisiopatología de la Obesidad y Nutrición] (CIBERObn) (Spain)

Sponsor details

Centro Hospitalario Universitario Santiago de Compostela

Edificio d Primera planta

Choupana s/n

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Sponsor type

University/education

Website

<http://www.ciberobn.es>

ROR

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

Funder(s)

Funder type

Government

Funder Name

Junta of Andalusia (Junta de Andalucía) (Spain) - Research Grant

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**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	01/05/2014		Yes	No