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

Submission date	Recruitment status	[_] Prospectively registered
22/04/2013	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
09/05/2013	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
03/06/2014	Other	

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 dInvestigació 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
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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