

Polyphenols bioavailability study on wine

Submission date 30/06/2014	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 06/08/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 06/08/2014	Condition category Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Polyphenols are the most abundant antioxidants in the diet and are found in a number of fruit and vegetables. Antioxidants are chemicals that mop up other, damaging, chemicals called free radicals. Free radicals can cause damage to the body's cells, which can eventually lead to a number of health problems including heart disease and cancer. The effects of polyphenols are dependent on how well they are absorbed (bioavailability) and how they react in, and are used by, the body. Numerous studies have found that people who drink a moderate amount of wine are less likely to have a heart attack or a stroke, among other things. In this study, we aim to find out whether the alcohol (ethanol) in wine increases the bioavailability of polyphenols.

Who can participate?

Healthy men, aged between 20-40 years, non-smokers, without previous history of cardiovascular disease, liver or kidney disease, homeostatic disorders, any several chronic diseases, high blood pressure or dyslipemia (abnormal amount of fat or cholesterol in the body), grape intolerance or allergic, alcoholism or other toxic abuse.

What does the study involve?

Participants are randomly allocated into one of three treatment (intervention) groups. For intervention 1, participants are given 339 mL of water to drink. For intervention 2, they are given 339 mL of wine. For intervention 3, they are given 417 mL of dealcoholized wine. Blood samples are taken at 15 min, 30 min, 1 hour, 2 hours, 3 hours, 4 hours, 5 hours, 6 hours and 24 hours after they have had their allotted drink. The first urine of the day before the start of the trial is also collected and then at 0 hours, 0-3 hours, 3-6 hours, 6-12 hours and 12-24 hours the day after they have had their allotted drink. Everyone will participate in all three intervention programmes, but with 3 day rest (wash-out period) in-between, when they are asked not to consume grapes or wine and to follow a polyphenol free diet the day before starting the next treatment.

What are the possible benefits and risks of participating?

There are no direct benefits to taking part in the study and no risks as long as the exclusion criteria are followed.

Where is the study run from?

Department of Nutrition and Food Science of the University of Barcelona (Spain)

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

March 2014 to November 2014

Who is funding the study?

1. Ministry of Economy and Competitiveness INNPRONTA (Spain)

2. CIBEROBN (Centro de Investigación Biomédica en Red Fisiopatología de la Obesidad y la Nutrición) (Biomedical Research Centre in Physiopathology of Obesity and Nutrition) (Spain)

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

IRB00003099

Study information

Scientific Title

Bioavailability of polyphenols from wine and dealcoholized wine: a cross-over, randomized and double blind trial

Acronym

BIOPOLIAL

Study objectives

Wine contains several phenolic compounds, which are known for their health benefits.
Hypothesis 1: Ethanol increases the bioavailability of phenolic compounds

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of University of Barcelona, 06/03/2014, Institutional Review Board
IRB00003099

Study design

Cross-over randomized double-blind trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Other

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 phenolic metabolites in urine

Interventions

Intervention 1: 339 ml of water

Intervention 2: 339 ml of wine

Intervention 3: 417 ml of dealcoholized wine

Before each intervention, participants will follow a 3-day washout period, avoiding consuming grape and wine, and the previous day follow a polyphenol-free diet.

Co-sponsor details:

CIBEROBN (Centro de Investigación Biomédica en Red Fisiopatología de la Obesidad y la Nutrición) (Biomedical Research Centre in Physiopathology of Obesity and Nutrition) (Spain)

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Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. Polyphenols will be identified through liquid chromatography coupled to Orbitrap mass spectrometry
2. Concentrations of polyphenols will be determined by liquid chromatography coupled to tandem mass spectrometry (LCMS/MS)

Secondary outcome measures

N/A

Overall study start date

15/03/2014

Completion date

15/11/2014

Eligibility**Key inclusion criteria**

Healthy adult males, aged 20-40 years

Participant type(s)

Patient

Age group

Adult

Sex

Male

Target number of participants

20

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 dyslipidemia
5. Grape intolerance or allergic
6. Smoking subjects
7. Alcoholism
8. Other toxic abuse

Date of first enrolment

15/03/2014

Date of final enrolment

15/11/2014

Locations

Countries of recruitment

Spain

Study participating centre

Food Science Department

Barcelona

Spain

08028

Sponsor information

Organisation

Ministry of Economy and Competitiveness INNPRONTA (Miguel Torres S.A) (Spain)

Sponsor details

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Sponsor type

Government

Funder(s)

Funder type

Research organisation

Funder Name

Ministry of Economy and Competitiveness INNPRONTA (Spain)

Funder Name

CIBEROBN (Centro de Investigación Biomédica en Red Fisiopatología de la Obesidad y la Nutrición) (Biomedical Research Centre in Physiopathology of Obesity and Nutrition) (Spain)

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