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Polyphenols bioavailability study on wine

Submission date
30/06/2014

Recruitment status
No longer recruiting

Registration date
06/08/2014

Overall study status
Completed

Last Edited
06/08/2014

Condition category
Other

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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 bodys 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

Contact name
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Contact details
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08028

Additional identifiers

Protocol serial number
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

Study type(s)
Other

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)
Instituto de Salud Carlos III
C/Monforte de Lemos 3-5
Pabellón 11
Planta 0
28029
Madrid
Spain
gerencia@ciberisciii.es

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
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)

Key secondary outcome(s))
N/A

Completion date
15/11/2014

Eligibility

Key inclusion criteria
Healthy adult males, aged 20-40 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Male

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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration