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DOSE-dependent response of polyphenols from GRAPE extract on polyphenols bioavailability

Submission date
01/07/2014

Recruitment status
No longer recruiting

Registration date
06/08/2014

Overall study status
Completed

Last Edited
22/01/2019

Condition category
Other

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

Plain English summary of protocol

Background and study aims
Grape pomaces are the solids left behind after the grapes have been pressed to make oils, juice or wine. They are known to be a rich source of polyphenols, chemicals that may be useful in protecting against a number of health problems or as ingredients for developing new interesting products. The effects of these compounds when consumed depend on how well they are absorbed (bioavailability) and also how they react in, and are used by, the body (pharmacokinetics). The aim of this study is to investigate the bioavailability and pharmacokinetics of these polyphenols by giving people different amounts of a grape extract in order to find out the most effective dose.

Who can participate?
Healthy adults 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 100 mL of light soda water and 400 mL of water to drink. For intervention 2, they are given 100 mL of grape extract, 100 mL of light soda water and 300 mL of water. For intervention 3, they are given 200 mL of grape extract, 100 mL of light soda water and 200 mL of water. 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?
1. Department of Nutrition and Food Science of the University of Barcelona (Spain)
2. Department of Internal Medicine, Hospital Clinic, Institut of Biomedical Research August Pi i Sunyer (IDIBAPS) (Spain)
3. University of Barcelona (Spain).

When is the study starting and how long is it expected to run for?
January 2014 to May 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
Determining the bioavailability of polyphenols from grape extract, their kinetics in plasma and their presence in urine to optimize the effective dose to observe any effect: a cross-over, randomized and double-blind trial

Acronym
DOSEGRAPE

Study objectives
Grapes contain several phenolic compounds, which are known for their health benefits.
Hypothesis 1: There is a close relationship between the intake dose and the polyphenols concentration in plasma
Hypothesis 2: Consumption of grape extract will produce an improvement in biochemical parameters

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the University of Barcelona, 10/06/2014, 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 polyphenols in urine and their kinetics in plasma

Interventions
Intervention 1: 100 ml of light soda water and 400 ml of water
Intervention 2: 100 ml of grape extract, 100 ml of light soda water and 300 ml of water
Intervention 3: 200 ml of grape extract, 100 ml of light soda water and 200 ml of water

Before each intervention, participants will follow a 3-day washout period, avoiding consuming grape and wine, and on the preceding day will 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
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Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Polyphenols will be identified through liquid chromatography coupled to Orbitrap mass spectrometry. Concentrations of polyphenols will be quantified by liquid chromatography coupled to tandem mass spectrometry (LCMS/MS). Polyphenols will be quantified at 0 to 24 hours of each intervention.

Secondary outcome measures
Before (0 hours) and after each intervention (6 hours) the following measures were taken:
1. Blood pressure
2. Body weight
3. Waist perimeter
4. Glucose
5. Lipid profile
6. Biomarkers of oxidative stress and systematic inflammation
7. Coagulation factor and vitamin levels

Overall study start date
02/01/2014

Completion date
01/05/2014

Eligibility

Key inclusion criteria
Healthy adults (females and males), aged 20-40 years

Participant type(s)
Patient

Age group

Adult

Sex
Both

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
02/01/2014

Date of final enrolment
01/05/2014

Locations

Countries of recruitment
Spain

Study participating centre
Nutrition and 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
Government

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2017	22/01/2019	Yes	No