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Assessment of different doses of polyphenols from dealcoholized red wine and red wine on blood pressure and endothelial function in subjects with metabolic syndrome and high cardiovascular risk.

Submission date
31/07/2015

Recruitment status
No longer recruiting

Registration date
18/09/2015

Overall study status
Completed

Last Edited
18/09/2015

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Antioxidants are substances, natural or man-made, that may prevent or delay damage to the cells in our bodies. They are found in many foods, including fruit and vegetables. Polyphenols are the most abundant antioxidants in the diet and are found in a wide variety of foods in nature. One of the foods most rich in these compounds is wine. It has been considered that the biological effects of these compounds depend on their bioavailability (the amount of the compound made available to the body after digesting) and kinetics of its exposure time in the human body. Many studies have found that moderate wine drinkers have a lower cardiovascular mortality and a lower incidence of myocardial infarction and stroke, among others. The aim of this study is to assess the usefulness of phenolic metabolites as specific biomarkers of wine consumption and observe whether the ethanol increases the bioavailability of phenolic compounds.

Who can participate?
Participants between 55 and 80 years of age without a history of cardiovascular disease, any of several chronic diseases or an allergy/intolerance to and grape and wine. They should also have at least 3 of the following: high blood pressure (hypertension), high blood glucose levels or needing to use antidiabetic drugs/insulin, high blood triglyceride and cholesterol levels and a waist circumference of at least 102cm for men and 88cm for women.

What does the study involve?
Participants are randomly allocated into one of 4 groups. Those in group 1 are asked to drink 375 mL/day of extra water for three months. Those in group 2 are asked to drink 375 mL/day of dealcoholized red wine for three months. Those in group 3 are asked to drink 375 mL /day of dealcoholized red wine enriched with a grape extract for three months. Women in group 4 are asked to drink 130 mL/day of red wine. Men in group 4 are asked to drink 260 mL/day of wine for

men for three months. All participants are requested to avoid consuming grape, wine and other alcoholized drinks for the 15 days leading up to the start of the study. All participants have a medical assessment is at the start and end of the study, which includes clinical history, dietary evaluation, anthropometric (body) measures, clinical blood pressure and 24-hour ambulatory blood pressure (that is, blood pressure taken over a 24 hour period as the participant goes about their daily activities), measurement of blood flow in brachial artery (major blood vessel in upper arm), full blood analysis (glucose, glycated hemoglobin, triglycerids, total cholesterol, HDLc, LDLc, lipoprotein (a)) and the collection of 24-hour urine sample.

What are the possible benefits and risks of participating?
There are no risks as long as the exclusion criteria are followed.

Where is the study run from?
The Department of Nutrition and Food Science of the University of Barcelona and the Department of Internal Medicine in the Hospital Clinic of Barcelona (Spain)

When is the study starting and how long is it expected to run for?
July 2015 to July 2016

Who is funding the study?
1. Ministry of Economy and Competitiveness, MINECO
2. Biomedical Research Centre in Physiopathology of Obesity and Nutrition (Ciberobn)

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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
IRB00003099

Study information

Scientific Title
Effects of bioactive compounds of dealcoholized red wine with two different polyphenol doses and red wine on blood pressure, biochemical parameters and cellular biomarkers related to atherosclerosis in subjects with metabolic syndrome. An open, randomized, parallel and controlled trial.

Acronym
POLYREDWIMES

Study objectives
Wine contains several phenolic compounds, which are known for its health benefits.

Aim 1: Compare the effects of consumption of dealcoholized red wine and dealcoholized red wine enriched with grape extract on anthropometric parameters, blood pressure, full blood analysis, levels of endothelial biomarkers and leukocyte cell-surface adhesion molecules in the subjects.

Aim 2: Compare the effects between dealcoholized red wine and regular alcoholized red wine on full blood analysis in subjects, anthropometric parameters, endothelial biomarkers, blood pressure and other cardiovascular risk factors.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Barcelona is Jordi Alberch Viè, 11/12/2014, ref: IRB00003099

Study design
Dietary intervention trial, parallel, randomized, open and controlled

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Metabolic Syndrome (MeTS)

Interventions
Participants are randomly allocated into one of 4 groups.
Intervention 1: 375 mL/day of extra water for three months (ICT).
Intervention 2: 375 mL/day of dealcoholized red wine for three months (IVS).
Intervention 3: 375 mL /day of dealcoholized red wine enriched with a grape extract for three months (IVE).
Intervention 4: 130 mL/day of red wine for women and 260 mL/day of wine for men during three months (IVI).

Intervention Type

Primary outcome measure
1. Leukocyte adhesion molecule expression: lymphocyte and monocyte adhesion molecules on these cells will be marked with monoclonal antibodies (MAb) conjugated with fluorescein-isothiocyanate (FITC) and phycoerythrin (PE) by direct double immunofluorescence. The MAb of the adhesion molecules used will be: anti-CD11a (LFA-1), anti-CD40L, anti-CD11b (Mac-1) (Bender MedSystems Diagnostics, Vienna), anti-Syalil Lewis (anti-CD15s) (Pharmingen, San Diego, CA), anti-CD49d (VLA-4) (Cytogmos). The monoclonal antibodies used to mark the T-lymphocytes will be anti-CD2 and monocytes, anti-CD14 (Caltag Laboratories, Burlingame, CA).
2. Decrease in the endothelial adhesion molecules, chemokines and interleukins with the increase in phenolic content of the treatment (IVI > IVE > IVS > ICT).
3. Improvement of endothelial function in all interventions, measuring endothelial progenitor cells and circulating endothelial cells.
All variables (primary and secondary outcomes) will be measured at baseline and after each intervention period.

Secondary outcome measures
1. All participants in the study will be clinically examined and subsequently signed an informed consent according accept their participation in the study
2. At the beginning and end of each intervention period a medical assessment will be performed which included: clinical history, dietary evaluation, anthropometric measures, clinical blood pressure and 24-hour ambulatory blood pressure, measurement of blood flow in brachial artery, full blood analysis (glucose, glycated hemoglobin, triglycerids, total cholesterol, HDLc, LDLc, lipoprotein (a)) and the collection of 24-h urine sample.
3. A 7-day food record validated nutritional questionnaire will be used at the beginning and end of the intervention to assess nutrient intake and to monitor adherence to the dietary recommendations. We will use the Food Processor Nutrition & Fitness software. Physical activity will also be evaluated with the Minnesota Leisure Time Physical Activity questionnaire which has also been validated in Spain
4. Bioavailability, identification and quantification polyphenols in plasma and urine to determine and compared new metabolites by LTQ-Orbitrap Mass Spectrometry and HPLC-MS/MS
5. Changes in urine metabolites (metabolomics)

Overall study start date
01/09/2015

Completion date
31/10/2016

Eligibility

Key inclusion criteria
Participants between 55 and 80 years of age and showed ≥ 3 of the following parameters that define the metabolic syndrome:
1. Hypertension (≥ 130/85 mm Hg or use of antihypertensive drugs)
2. Impaired glucose tolerance (glycemia ≥ 100 mg/dL or use of antidiabetic drugs and/or insulin)
3. Serum triglyceride concentration ≥150 mg/dL
4. Plasma HDL cholesterol concentrations ≤ 40 mg/dL (men), ≤ 50 mg/dL (women)
5. Waist circumference ≥ 102 cm (men), ≥ 88 cm (women)

Participant type(s)
Other

Age group
Mixed

Sex
Both

Target number of participants
80

Key exclusion criteria
Healthy adults (males and females) or with:
1. Previous history of cardiovascular disease
2. Any several chronic diseases
3. Grape and wine intolerance or allergic
4. Alcoholism
5. Other toxic abuse

Date of first enrolment
01/10/2015

Date of final enrolment
31/07/2016

Locations

Countries of recruitment
Spain

Study participating centre
Department of Nutrition and Food Science of the University of Barcelona (Barcelona, Spain) and the Department of Internal Medicine in the Hospital Clinic of Barcelona.

Barcelona
Spain
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Sponsor information

Organisation
Bodegas Torres

Sponsor details
Vilafranca del Penedès
Barcelona
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Sponsor type
Industry

Website
http://www.torres.es/

Organisation
Biomedical Research Centre in Physiopathology of Obesity and Nutrition (Ciberobn)

Sponsor details
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Sponsor type
Research organisation

Website
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Organisation
Ministry of Economy and Competitiveness

Sponsor details

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Sponsor type
Government

Funder(s)

Funder type
Government

Funder Name
Ministerio de Economía y Competitividad

Alternative Name(s)
Ministry of Economy and Competitiveness, MINECO, MEC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Spain

Funder Name
Biomedical Research Centre in Physiopathology of Obesity and Nutrition (Ciberobn)

Results and Publications

Publication and dissemination plan

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available