ISRCTN38867650 https://doi.org/10.1186/ISRCTN38867650

The pharmacokinetics and potential health effects of champagne wine in human subjects

Submission date 09/07/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 07/08/2009	**Overall study status** Completed	
Last Edited 31/01/2013	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Jeremy Paul Edward Spencer

Contact details
Department of Food and Nutritional Sciences
School of Chemistry, Food Biosciences and Pharmacy
The University of Reading
PO Box 226, Whiteknights
Reading
United Kingdom
RG6 6AP
+44 (0)118 378 8724
j.p.e.spencer@reading.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00937313

Secondary identifying numbers

N/A

Study information

Scientific Title
The pharmacokinetics and potential health effects of champagne wine in human subjects: a placebo-controlled randomised cross-over human trial

Study objectives
Determine whether there is a link between champagne wine intake and changes in cardiovascular disease (CVD) risk factors, including blood lipid profile, platelet function and oxidative status. The study will also establish the absorption of polyphenol uptake following consumption of champagne wine.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The University of Reading Research Ethics Committee approved on the 8th May 2007 (ref: 07/16)

Study design
Placebo-controlled randomised cross-over human trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

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
Cardiovascular disease (CVD) risk factors

Interventions
Acute consumption of three glasses of champagne wine (375 ml) or the equivalent alcohol with sparkling mineral water as the control (placebo) within a 10-minute period. This amount of champagne contains 4.5 units of alcohol, which is above the legal limit for operating a car or other machinery. Following a washout period of 28 days, volunteers returned to the unit to complete the second arm of the study where the procedure above was repeated.

Subjects were assessed for anthropometric measurements and provided a urine sample prior baseline Laser Doppler Imaging with iontophoresis (LDI) measurements. Subjects were then cannulated and a baseline blood sample was collected. The intervention was then performed. Following a standardised breakfast blood samples were collected at: 15, 30, 45, 60, 120, 180, 240, 300, 360 and 480 minutes post-consumption and pooled urine samples were collected over 3 x 8-hour periods. A standardised breakfast and lunch were also consumed at 15 and 200 minutes post beverage. LDI measurements were carried out at 120, 240, 360 and 480 minutes. Subjects also provided 24-hour and 32-hour blood and urine samples.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Assessment of endothelial function by Laser Doppler Imaging with iontophoresis, at baseline and 28 days
2. Blood assessment of lipid profile, inflammatory markers, plasma antioxidant and oxidant capacity, liver enzyme and metalloproteinase blood concentrations, measured at baseline, 15, 30, 45, 60, 120, 180, 240, 300, 360 and 480 minutes post-consumption at each intervention point

Secondary outcome measures
Bioavailability of phytochemicals and metabolite excretion, pooled urine samples were collected over 3 x 8-hour periods, at 24 hours and 32 hours at each intervention point

Overall study start date
01/09/2008

Completion date
01/08/2009

Eligibility

Key inclusion criteria
1. Healthy male and female subjects
2. Aged between 20 and 65 years
3. Body mass index (BMI) between 19 and 25 kg/m^2
4. Normal concentrations of liver enzymes (aspartate aminotransferase [AST], alanine aminotransferase [ALT], gamma-glutamyl transpeptidase [gamma-GT])
5. Normal haemoglobin, hematocrit and leucocyte counts
6. Absence of glucose and protein in urine

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
15

Key exclusion criteria
1. Diabetes mellitus
2. Any form of liver or gastrointestinal disorder
3. Low body mass index [BMI] (less than 19 kg/m^2)
4. High blood pressure (greater than 150/90 mmHg)
5. Anaemia
6. Gall bladder problems
7. Present illness
8. Taking dietary supplements
9. Vigorous exercise (greater than 3 x 20 minutes/week)
10. Alcohol consumption more than 120 g (women) and 168 g (men) per week
11. Pregnant or lactating females

Date of first enrolment
01/09/2008

Date of final enrolment
01/08/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Food and Nutritional Sciences
Reading
United Kingdom
RG6 6AP

Sponsor information

Organisation
Biotechnology and Biological Sciences Research Council (BBSRC) (UK)

Sponsor details

Polaris House
North Star Avenue
Swindon
United Kingdom
SN2 1UH
+44 (0)1793 413200
external.relations@bbsrc.ac.uk

Sponsor type
Research council

Website
http://www.bbsrc.ac.uk/index.html

ROR
https://ror.org/00cwqg982

Funder(s)

Funder type
Research council

Funder Name
Biotechnology and Biological Sciences Research Council (BBSRC) (UK) (ref: BB/F008953/1; BB/C518222/1; BB/G005702/1)

Alternative Name(s)
UKRI - Biotechnology And Biological Sciences Research Council, BBSRC UK, BBSRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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	01/04/2010		Yes	No