Effects of moderate red wine consumption on antioxidant and redox-sensitive immunological parameters in healthy volunteers

Submission date	Recruitment status No longer recruiting	Prospectively registered		
27/04/2005		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
09/05/2005	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
15/02/2008	Other			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof Roland Goerlich

Contact details

Institute for Molecular Biotechnology RWTH Aachen University Worringerweg 1 Aachen Germany 52074 +49 (0)241 8026627 goerlich@molbiotech.rwth-aachen.de

Additional identifiers

Protocol serial number N/A

Study information

Scientific Title

Study objectives

Moderate consumption of red wine shows antioxidant activity in vivo and modulates functions of the specific and unspecific immune response. The effects of native and dealcoholised red wine are compared to control intervention (short term: water; dietary intervention: no study drink).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the ethics committee of the University of Bonn.

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Oxidative stress in healthy subjects

Interventions

- 1. One single dose (one glass) of red wine, dealcoholised red wine or water in a fasting state (Single dose analysis) OR
- 2. One glass of red wine, dealcoholised red wine or no special drink (controls) daily after dinner for a period of 6 weeks (dietary intervention trial)

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

- 1. Concentration of total phenolic compounds in plasma (folin assay)
- 2. Deoxyribonucleic acid (DNA) strand breaks in peripheral leukocytes (single cell gel electrophoresis)
- 3. Antioxidant capacity in plasma (trolox equivalent antioxidant capacity)
- 4. Apoptosis of PHA activated T lymphocytes (annexin-V binding test)
- 5. Phagocytosis in monocytes and granulocytes (Phagotest® test kit)
- 6. Respiratory burst in monocytes and granulocytes (Bursttest® test kit)

Key secondary outcome(s))

- 1. Vitamin C concentration in plasma a-tocopherol concentration in serum (dietary intervention trial only)
- 2. Concentration of uric acid, albumin and bilirubin in plasma

Completion date

31/08/2001

Eligibility

Key inclusion criteria

Healthy, normal-weight male and female subjects between 18 and 50 years of age.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

- 1. Pregnancy and lactation: women not taking oral contraceptives underwent a pregnancy test to exclude an unknown pregnancy before starting the intervention
- 2. Known diseases of the liver and pancreas or dysfunctions of the gastro-intestinal tract associated with maldigestion or malabsorption
- 3. Hypertension
- 4. Dysfunctions of the lipid metabolism
- 5. Hyperuricaemia/gout
- 6. Kidney dysfunctions
- 7. Autoimmune diseases
- 8. Diabetes mellitus type I or type II
- 9. Acute infectious diseases
- 10. Eating disorders
- 11. Allergy to hen's eggs (albumen used as finings in red wine)
- 12. Alcohol abuse (more than 40 g/day) or previous addiction to alcohol
- 13. Drug abuse
- 14. Tobacco smoking during the last 6 months prior to the study
- 15. Regular intake of pharmaceuticals, which influence the immune system and/or the antioxidant capacity in plasma (anti-inflammatory drugs including cortisol containing medications, immune stimulants) as well as intake of drugs which might cause adverse affects by interacts with alcohol
- 16. Intake of nutritional supplements e.g. multivitamins, supplements containing vitamin A, C and /or vitamin E, fish oil or red wine preparations, bioactive concentrates
- 17. Excessive exercising (competitive athletes) defined as greater than 10 hours strenous exercise per week
- 18. Limited contractual capability
- 19. Every other state opposed to participation in the study stated by the medical supervisor

20. Participation in any other clinical trial (ongoing or completed less than 30 days prior to the present study)

Date of first enrolment

01/05/2001

Date of final enrolment

31/08/2001

Locations

Countries of recruitment

Germany

Study participating centre Institute for Molecular Biotechnology Aachen Germany 52074

Sponsor information

Organisation

Institute for Molecular Biotechnology (Germany)

Funder(s)

Funder type

Research organisation

Funder Name

German Wine Academy (Deutsche Weinakademie) (Germany) - Funding

Funder Name

Landesgraduiertenfoerderung Nordrheinwestfalen (Germany) - Scholarship

Funder Name

Friedrich-Ebert-Stiftung (Germany) - Scholarship

Funder Name

Staatliche Weinbaudomaene Marienthal (Germany) - Wine

Results and Publications

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	14/11/2005		Yes	No