ISRCTN68505294 https://doi.org/10.1186/ISRCTN68505294

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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
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)

Secondary outcome measures
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

Overall study start date
01/05/2001

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
105

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)

Sponsor details
RWTH Aachen University
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Sponsor type
Research organisation

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

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	14/11/2005		Yes	No