

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

<b>Submission date</b> 27/04/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 09/05/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 15/02/2008	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## 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?
<a href="#">Results article</a>	Results	14/11/2005		Yes	No