In Vino Veritas (IVV): a pilot randomised trial comparing long-term effects of red wine and white wine on the biomarkers of atherosclerosis

Submission date	Recruitment status	Prospectively registered
05/11/2010	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
20/12/2010	Completed	Results
Last Edited	Condition category	Individual participant data
20/12/2010	Circulatory System	[] Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof Milos Taborsky

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

In Vino Veritas (IVV) a long-term, prospective, multicentre, randomised trial comparing long-term effects of red wine and white wine on the biomarkers of atherosclerosis

Acronym

IVV

Study objectives

Regular consumption of Moravian wine will improve the profile of laboratory parameters associated with the development of atherosclerosis.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The Ethics Committee of University Hospital Olomouc approved on the 16th November 2009 (ref: 124/09)

Study design

Long term prospective multicentre randomised parallel group trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Quality of life

Participant information sheet

Not available in web format, please use contact Ms Dagmar Strnkova [dagmar.strnkova@fnol.cz] to request a patient information sheet

Health condition(s) or problem(s) studied

Primary prevention of atherosclerosis in individuals at mild to moderate

Interventions

Eligible individuals will be randomised to regular drinking of either red wine (Pinot Noir, 2008, Moravia, Czech Republic) or white wine (Chardonnay-Pinot, 2008, Moravia, Czech Republic) for 12 months.

- 1. Women with body with body weight less than 70 kg: 0.2 litre per day
- 2. Women over 70 kg and men: 0.3 litre per day

Participants will be followed for 12 months on an intention-to-treat basis, and monitored on a continuous basis for 24 months.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Level of high density lipoprotein (HDL) cholesterol, measured at 6 and 12 months.

Secondary outcome measures

- 1. Total and low density lipoprotein (LDL) cholesterol
- 2. Triglycerides
- 3. Oxidized LDL
- 4. C-reactive protein (CRP)
- 4. Advanced oxidation protein product (AOPP)
- 5. Myeloperoxidase
- 6. Interleukin 6 (IL-6)
- 7. IL-18
- 8. Matrix metalloproteinases
- 9. Glutathione s-transferase
- 10. Monocyte chemoattractant protein 1
- 11. Solube CD40L
- 12. Fatty acid binding protein

Outcomes will be measured at 6 and 12 months.

Overall study start date

01/12/2010

Completion date

01/12/2012

Eligibility

Key inclusion criteria

- 1. Age over 18 years
- 2. No symptoms of atherosclerosis
- 3. Mild to moderate risk of cardiovascular disease

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

120

Key exclusion criteria

- 1. Acute or chronic inflammatory disease
- 2. Liver disease
- 3. Renal disease

Date of first enrolment

01/12/2010

Date of final enrolment

01/12/2012

Locations

Countries of recruitment

Czech Republic

Study participating centre Olomouc University Hospital

Olomouc Czech Republic 77520

Sponsor information

Organisation

Olomouc University Hospital (Czech Republic)

Sponsor details

First Clinic of Internal Medicine
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Sponsor type

Hospital/treatment centre

ROR

https://ror.org/01jxtne23

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Olomouc University Hospital (Czech Republic)

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