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

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

1-9-2010

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
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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