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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

Registration date
20/12/2010

Overall study status
Completed

Last Edited
20/12/2010

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

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
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)

Primary study design
Interventional

Study design
Long term prospective multicentre randomised parallel group trial

Study type(s)
Quality of life

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

Key secondary outcome(s)

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.

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

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)

ROR
https://ror.org/01jxtne23

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Olomouc University Hospital (Czech Republic)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration