

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

<b>Submission date</b> 05/11/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 20/12/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 20/12/2010	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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)

**Study design**

Long term prospective multicentre randomised parallel group trial

**Primary study design**

Interventional

**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 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. Soluble 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

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
	Participant information sheet				

