# Anti-inflammatory effects of alcohol and polyphenolic content of beer

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>		
07/09/2010	No longer recruiting	Protocol		
Registration date	Overall study status	Statistical analysis plan		
04/10/2010	Completed	[X] Results		
<b>Last Edited</b> 04/09/2014	Condition category Circulatory System	Individual participant data		

#### Plain English summary of protocol

Not provided at time of registration

#### Contact information

#### Type(s)

Scientific

#### Contact name

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#### Additional identifiers

**EudraCT/CTIS** number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Beer-01-2010

# Study information

#### Scientific Title

Scientific basis of beneficial effects of moderate beer consumption in the cardiovascular system: anti-inflammatory effects of alcohol and polyphenolic content of beer

#### **Study objectives**

The benefit of the main components of beer, namely ethanol and polyphenolic content is synergistic. No adverse events will be observed.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Institutional Review Board of the Hospital Clinic of Barcelona, 20/07/2010

#### Study design

Open randomised crossover controlled clinical trial

#### Primary study design

Interventional

#### Secondary study design

Randomised controlled trial

#### Study setting(s)

Hospital

#### Study type(s)

Quality of life

#### Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

#### Health condition(s) or problem(s) studied

**Arteriosclerosis** 

#### **Interventions**

Intervention 1: 92 ml/day of gin (28 g ethanol/day)

Intervention 2: 660 ml/day of lager beer (28 g ethanol/day)

Intervention 3: 990 ml/day of dealcoholised lager beer (equivalent amount of polyphenols to

660 ml of beer)

Initial wash-out period (15 days) First intervention - 28 days Second intervention - 28 days Third intervention - 28 days

#### **Intervention Type**

Drug

#### Phase

Not Applicable

#### Drug/device/biological/vaccine name(s)

Beer

#### Primary outcome measure

- 1. Endothelial function with a color Doppler Toshiba PowerVision ultrasound apparatus using multifrequency transducers (B-mode, 7.5 to 10 MHz; Doppler, 3.75 MHz).
- 2. Leukocyte adhesion molecule expression: lymphocyte and monocyte adhesion molecules on these cells will be marked with monoclonal antibodies (MAb) conjugated with fluoresceinisothiocyanate (FITC) and phycoerythrin (PE) by direct double immunofluorescence. The MAb of the adhesion molecules used will be: anti-CD11a (LFA-1), anti-CD40L, anti-CD11b (Mac-1) (Bender MedSystems Diagnostics, Vienna), anti-Syalil Lewis (anti-CD15s) (Pharmingen, San Diego, CA), anti-CD49d (VLA-4) (Cytogmos). The monoclonal antibodies used to mark the T-lymphocytes will be anti-CD2 and monocytes, anti-CD14 (Caltag Laboratories, Burlingame, CA).

  3. Soluble adhesion molecules: the following serum soluble adhesion molecules will be determined by enzyme-linked immunosorbent assay (ELISA) kits: soluble intercellular adhesion molecule-1 (sICAM-1), soluble vascular adhesion molecule 1 (sVCAM-1), sE-selectin, and sP-selectin, as well as soluble monocyte chemotactic protein-1 (sMCP-1), tumour necrotising factor-
- 4. Nuclear Factor Kappa B by western blot of peripheral blood mononuclear cells.

alpha (TNF-a), and interleukin B (IL-1B) (Immunotech)

5. Genes and proteins involved in inflammatory response will be determined by real time polymerase chain reaction (PCR) and Western blot analysis (MCP-1, TF and TFPI, as markers of inflammation and LRP and the LDL receptor as lipoproteic receptors). Moreover, the expression metalloproteases and their activity will also be analysed.

All variables (primary and secondary outcomes) will be measured at baseline and after each intervention period.

#### Secondary outcome measures

- 1. Medical record: a complete medical record will be obtained from all participants, which included data on alcohol intake, smoking and dietary habits. Blood pressure and heart rate will be measured with an electronic apparatus Omron HEM-705CP (Netherlands).
- 2. Nutrition assessment and general analyses: all participants will complete a validated nutritional questionnaire at baseline to determine the total quantity of calories ingested in the previous month as well as the proportion corresponding to carbohydrates, lipids and proteins. Overall nutrition will be determined by percentage of ideal weight, lean body mass and body mass index. Waist perimeter will be measured. The proteic nutrition will be determined on the basis of the following parameters: haemoglobin, total lymphocyte count, total proteins, albumin, prealbumin, transferrin and retinol-binding protein. Serum and intraerythrocytary folic acid concentrations will be measured, as well as serum vitamin A, B1, B12, C, E, B-carotenes, Zn, Mg and Se concentrations. Moreover, the following measurements will also be obtained: red blood cell count, hematocrit, mean corpuscular volume, leukocyte count, glucose, creatinine, electrolytes, uric acid, transaminases, lactate dehydrogenase, alkaline phosphatase, gammaglutamyl transpeptidase and bilirubin.
- 3. Coagulation tests: the following parameters will also be determined: platelet count, prothrombin time, and plasma fibringen.
- 4. Serum lipoproteins and others: total cholesterol, triglycerides, cHDL, cLDL, Apo A1, Apo B,

lipoprotein (a) and homocysteine will be determined.

5. Diet and exercise monitoring: all participants will follow an isocaloric diet prepared according to their personal preferences. The diet will be strictly monitored during the study. Diet compliance will be assessed from 7-days diet records administered before each evaluation. This assessment will be administered by trained personnel. The foods ingested will be converted into nutritional values with the aid of the Professional Diet Balancer software (Cardinal Health Systems, Inc., Edina, MN). Physical activity will also be evaluated with the Minnesota Leisure Time Physical Activity questionnaire which has also been validated in Spain. Control of the diet and physical exercise will be carried out before and after each intervention, the same day on which the clinical examinations are performed and blood is withdrawn for immunologic studies.

All variables (primary and secondary outcomes) will be measured at baseline and after each intervention period.

#### Overall study start date

01/10/2010

#### Completion date

01/10/2011

# Eligibility

#### Key inclusion criteria

- 1. Males between 55 and 70 years old
- 2. No documented cardiovascular disease (ischaemic heart disease angina or recent or old myocardial infarction or previous or cerebral vascular accident, peripheral vascular disease)
- 3. Diabetes mellitus, or three or more of the following risk factors:
- 3.1. Current smoking
- 3.2. Hypertension
- 3.3. Hypercholesterolaemia (low density lipoprotein [LDL]-cholesterol greater than 160 mg/dl)
- 3.4. High density lipoprotein (HDL)-cholesterol less than 40 mg/dl
- 3.5. Overweight or obese (body mass index greater than 25 kg/m^2)
- 3.6. Family history of premature coronary heart disease
- 4. Participant gives signed informed consent

#### Participant type(s)

Patient

#### Age group

Adult

#### Sex

Male

#### Target number of participants

50

#### Key exclusion criteria

1. Previous history of cardiovascular disease (ischaemic heart disease - angina or recent or old myocardial infarction, cerebral vascular accident, or peripheral vascular disease)

- 2. Any severe chronic disease
- 3. Alcoholism
- 4. Other toxic abuse

## Date of first enrolment

01/10/2010

#### Date of final enrolment

01/10/2011

### **Locations**

#### Countries of recruitment

Spain

# Study participating centre Department of Internal Medicine

Barcelona Spain 08036

# Sponsor information

#### Organisation

Cerveceros de España (Spain)

#### Sponsor details

C/ Almagro, 24 2° Izqda Madrid Spain 28010

#### Sponsor type

Industry

#### Website

http://www.cerveceros.org/

#### ROR

https://ror.org/02skr9c69

# Funder(s)

#### Funder type

Industry

#### Funder Name

Cerveceros de España (Spain)

# **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

#### **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2014		Yes	No
Results article	results	01/04/2014		Yes	No
Results article	results	01/01/2015		Yes	No