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Anti-inflammatory effects of alcohol and polyphenolic content of beer

Submission date	Recruitment status	[_] Prospectively registered
07/09/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
04/10/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
04/09/2014	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
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 fluorescein-isothiocyanate (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-alpha (TNF-a), and interleukin B (IL-1B) (Immunotech)
4. Nuclear Factor Kappa B by western blot of peripheral blood mononuclear cells.
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, gamma-glutamyl transpeptidase and bilirubin.
3. Coagulation tests: the following parameters will also be determined: platelet count, prothrombin time, and plasma fibrinogen.
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 2º 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