ISRCTN47732406 https://doi.org/10.1186/ISRCTN47732406

Effect of wild blueberry intake on reduction of cardiovascular risk factors

Submission date 24/10/2011	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 09/12/2011	**Overall study status** Completed	
Last Edited 07/10/2016	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
Cardiovascular disease (CVD) is a general term for conditions affecting the heart or blood vessels. The incidence of CVD is increasing worldwide. Diets rich in fruits and vegetables are among the recommended lifestyle changes that decrease the risk of CVD. Blueberries are a rich source of anthocyanins that have been found to improve blood vessel function and protect against DNA damage. The aim of this study is to investigate the effect of a wild blueberry drink on blood vessel function and DNA damage in people with at least one risk factor for CVD.

Who can participate?
Men aged 40-60 with at least one risk factor for CVD (smoking, high blood pressure, high cholesterol or overweight)

What does the study involve?
Participants are randomly allocated to drink either a wild blueberry drink or a placebo drink (a similar drink but not containing the active ingredients) daily for 6 weeks. After a 6-week break participants then swap to the other drink for a further 6 weeks. Blood vessel function, DNA damage, and other factors such as blood pressure and blood glucose (sugar) and lipid (fat) levels, are measured before and after consuming the wild blueberry or placebo drinks for 6 weeks.

What are the possible benefits and risks of participating?
Drinking the wild blueberry drink may improve blood vessel function and protect against DNA damage. No risks are expected.

Where is the study run from?
University of Milan (Italy)

When is the study starting and how long is it expected to run for?
October 2009 to May 2010

Who is funding the study?
Cariplo Foundation (Italy)

Who is the main contact?
Prof. Marisa Porrini

Contact information

Type(s)
Scientific

Contact name
Prof Marisa Porrini

Contact details
University of Milan
Faculty of Agriculture
DiSTAM-Department of Food Science and Microbiology Division of Nutrition
Via G. Celoria 2
Milan
Italy
20133

Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Use of biosensors within a multidisciplinary approach for the study of degenerative disease prevention through diet

Acronym
WBH1

Study objectives
Oxidative stress is believed to be involved in vascular function, oxidative damage and inflammation in cardiovascular (CVD) diseases. Subjects with CVD risk factors such as: smoking, pre-hypertension, high serum cholesterol, low high density lipoprotein (HDL) cholesterol, high low density lipoprotein (LDL) cholesterol, high triglycerides and overweight, constitute a good model to examine the protective role of an anthocyanin (ACN) rich diet in this population group. We hypothesize that a diet enriched with wild blueberries could improve endothelial function (i. e. improved peripheral arterial tone) and cell protection against oxidative damage (e.g. DNA damage) by providing ACNs and related metabolites able to affect directly or indirectly such functions. Moreover, the regular intake of these compounds could also modulate other markers related to oxidative stress and the inflammatory process.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the University of Milan, 10/01/2008

Study design
Randomized repeated measures crossover design

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Risk factors for cardiovascular disease

Interventions
Participants were randomized in a cross-over design and received a wild blueberry (25 g freeze-dried wild blueberry providing 375 mg of anthocyanins, in 250 mL of water) or a placebo drink (sensory characteristics similar to the wild blueberry drink, with the same amount of sugars but without polyphenols/anthocyanins) for six weeks each. The two experimental periods were separated by a six week wash-out period.

Intervention Type
Other

Primary outcome(s)
The following outcomes were measured at the beginning and at the end of each experimental period:
1. The improvement of peripheral vascular function (measured by a non-invasive pletismographic method)
2. The reduction of endogenous oxidized DNA bases and the resistance to H2O2-induced DNA damage (evaluated in blood mononuclear cells by Comet assay)

Key secondary outcome(s))
The following outcomes were measured at the beginning and at the end of each experimental period:
1. Body mass index (BMI)
2. Nutritional biomarkers [anthocyanins (ACNs), vitamin C, folate, vitamin B12, glutathione (GSH/GSSG)]
3. Changes in blood pressure (diastolic and systolic blood pressure) and markers of endothelial function: [soluble vascular adhesion molecule concentration (sVCAM-1), total nitric oxide (NO)].
4. Changes in glucose and lipid profile (triglycerides, total cholesterol, HDL-cholesterol, LDL-cholesterol)
5. Changes in markers of inflammation [C-reactive protein (CRP), tumor necrosis factor alpha (TNF-¦Á), interleukin-6 (IL-6)]
6. Modulation of cell DNA repair activity and enzyme activities [glutathione-S-transferase (GST)-activity, superoxide dismutase (SOD) and glutathione peroxidase (GSH-px)]
7. Changes in serum creatinine, S-aspartate aminotransferase, S-alanine aminotransferase and S-gamma glutamiltransferase

Completion date

15/05/2010

Eligibility

Key inclusion criteria
1. Wish to participate
2. Male subjects
3. Healthy subjects with at least one risk factor for cardiovascular disease such as: smoking (more than 10 cigarettes/day), pre-hypertension (systolic pressure 120-139 mm Hg and diastolic pressure between 80-89 mm Hg), high serum cholesterol (more than 200 mg/dl), low HDL cholesterol (lower than 40 mg/dl), high LDL cholesterol (more than 130 mg/dl), high triglycerides (more than 150 mg/dl) and overweight body mass index (BMI) more than 25)
4. Signed informed consent

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Sex
Male

Key exclusion criteria
1. Individuals with secondary hypertension or obesity (BMI > 30)
2. Diabetes, renal insufficiency, known food allergies, chronic constipation, diarrhea or any other gastrointestinal problem, or diseases
3. Use of any drugs, supplements, specific prebiotics or prebiotics or medications at least one month before the beginning of the experiment
4. Volunteers who did not eat fruits and vegetables
5. Difference in dietary habits in particular for food rich in antioxidant compounds: high (> 5 portions/day) or low (<2 portions/day) intake of fruit and vegetables
6. Habitual alcohol consumption (> 3 drinks per week)
7. Vegetarian, vegan or macrobiotic
8. Subjects with specific aversion to blueberries or their products

Date of first enrolment
03/10/2009

Date of final enrolment
15/05/2010

Locations

Countries of recruitment
Italy

Study participating centre
University of Milan
Milan
Italy
20133

Sponsor information

Organisation
University of Milan (Italy)

ROR
https://ror.org/00wjc7c48

Funder(s)

Funder type
Research organisation

Funder Name
Cariplo Foundation (Italy) - (Research grant 2007-5810)

Alternative Name(s)
Cariplo Foundation

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Italy

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?
Results article	results	01/04/2013		Yes	No