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Effect of anthocyanin-rich food intake on reduction of cardiovascular risk factors

Submission date
26/02/2014

Recruitment status
No longer recruiting

Registration date
05/06/2014

Overall study status
Completed

Last Edited
10/05/2021

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
As you breathe and you cells produce energy, your body constantly reacts with the oxygen in it and highly reactive molecules are produced. These molecules are called free radicals. These free radicals, in turn, will interact with other molecule within your cells. This can cause damage, termed oxidative damage, to your body. Oxidative damage or stress is thought to be a contributing factor to a number of chronic and degenerative diseases, including cardiovascular diseases (e.g. heart disease, stroke and peripheral arterial disease). Diet plays a crucial role in preventing these diseases. Eating fruit and vegetables on a regular basis reduces the risk factors associated to oxidative stress and cardiovascular disease. This is thought to be because they contain antioxidants, such as polyphenols and anthocyanin (ACN), that protect against oxidative stress by neutralising, or mopping up the free radicals that can cause so much damage. The aim of the study is to investigate the role of polyphenol/ACN-rich foods (for example, blueberries) in reducing oxidative stress and therefore, for example, inflammation and damage to the cells lining the arteries (endothelial cells) in healthy people exposed to risk factors for cardiovascular disease.

Who can participate?
Healthy men and women between the age of 20-35 years, who are also moderate smokers (about 10-15 cigarettes a day), take moderate exercise (25-30 minutes of brisk walking or jogging a day) and drink up to 14 drinks on a weekly basis.

What does the study involve?
There are two parts to the trial.
Study 1 (Acute study): Each participant is randomly placed in one of two groups. One group is given fresh blueberries or fruit juice rich in polyphenol/ACNs and the other a placebo (a drink or food that do not contain polyphenol/ACN) for one day. Then, the treatment is stopped for ten days after which, group 2 is given the polyphenol/ACN-rich food/drink and group one take the placebo for another day.
Study 2 (Chronic study): Similar to study 1, but this time the participants are asked to eat/drink the polyphenol/ACN rich blueberries products or placebos for 6 weeks and the experiment stopped for a further 6 weeks before the groups swap over.

What are the possible benefits and risks of participating?
Benefits: The eating of the polyphenol/ACN rich blueberries should reduce oxidative stress and have a positive effect on the risk of disease associated with the damage done by free radicals.
Risks: There are no risk foreseen for people taking part in the study.

Where is the study run from?
Department of the University of Milan, Italy

When is the study starting and how long is it expected to run for?
May 2013 to May 2014.

Who is funding the study?
The study is partially supported by research grants from Cariplo Foundation and intramural funding of the Department.

Who is the main contact?
Prof. Marisa Porrini
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

In vivo study of the effects of anthocyanin (ACN) and polyphenol-rich foods on the modulation of biomarkers related to oxidative stress

Acronym
ACN-foods & function

Study objectives
Oxidative stress is believed to be involved in vascular dysfunction, oxidative damage to macromolecules (i.e. DNA damage) and inflammation. Subjects, above all those exposed to oxidative stress and/or risk factor for cardiovascular disease, constitute a good model to examine the protective role of an anthocyanin (ACN) rich diet in this population group. We hypothesized that ACN-rich foods [i.e. blueberries (BB)] could improve cell protection against oxidative damage (e.g. DNA damage) and endothelial function (i.e. improved peripheral arterial tone-RHI) by providing bioactive compounds able to affect directly or indirectly such functions. Moreover, the acute or 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)
University of Milan Ethics Committee 10/01/2008, reference: (allegato 2 - http://www.unimi.it /ateneo/28149.htm)

Study design
Acute and chronic randomized placebo controlled repeated measures crossover design

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Diagnostic

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
Oxidative stress and /or risk factors for cardiovascular disease

Interventions
Study 1- Acute study: Participants are randomized in a cross-over design and receive blueberry (i. e. fresh whole berries or juice, providing at least 300mg of ACNs) or placebo (i.e. drink/food without polyphenols/ACNs) in a single day. Each experimental period will be separated by a 10-day wash-out period.

Study 2- Chronic study: Participants are randomized in a cross-over design and will receive blueberry (i.e. fresh whole berries/juice, providing at least 300mg/day of ACNs) or placebo (i.e. drink/food without polyphenols/ACNs) for at least 6 weeks. Each experimental period will be separated by 6-week wash-out period.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. The reduction of endogenous oxidized DNA bases and the resistance to H2O2-induced DNA damage (evaluated in blood mononuclear cells by Comet assay)
2. Improvement of peripheral vascular function (measured by a non-invasive pletismographic method).
The outcomes are measured before and after the blueberry or placebo treatment and at specific time points.

Secondary outcome measures
The following outcomes are measured before and after the blueberry or placebo treatment for the chronic study, and at specific time points for the acute study (before blueberry/placebo intake and after 2 h, 2 h 30 min, 3 h, 3h 30 min, and 24h).
1. Reduction of endogenous oxidized DNA bases and the resistance to oxidatively-induced DNA damage (evaluated in blood mononuclear cells by Comet assay)
2. Nutritional biomarkers [i.e. ACNs, vitamin C, folate, glutathione (GSH/ GSSG)]
3. Changes in blood pressure (diastolic and systolic blood pressure) and markers of endothelial function [i.e., soluble vascular adhesion molecule concentration (sVCAM-1), vascular endothelial growth factor (VEGF), total nitric oxide (NO)]
4. Changes in glucose and lipid profile [triglycerides, total cholesterol, high density lipoprotein (HDL)-cholesterol, low density lipoprotein (LDL)-cholesterol]
5. Changes in markers of inflammation [i.e., C-reactive protein (CRP), interleukin-8 (IL-8)]

Overall study start date
01/05/2013

Completion date
01/05/2014

Eligibility

Key inclusion criteria
1. Healthy men/women smokers (20-35 years of age)
2. Moderate smoking (about 10-15 cigarette/day)
3. Moderate physical activity (25-30 min per day of brisk walk or jog)
4. Moderate alcohol consumption (up to 14 drinks per week)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
At least 20 subjects

Total final enrolment
16

Key exclusion criteria
1. Individuals with hypertension (systolic blood pressure > 140 mm Hg and/or diastolic blood pressure > 90 mm Hg), hyperglycemia (> 180 mmol/L), hypertriglyceridemia (≥1.69 mmol/L) and hypercholesterolemia (≥5.17 mmol/L), low HDL cholesterol (<1.03 mmol/L), high LDL cholesterol (≥3.36 mmol/L), overweight (BMI >25)
2. History of cardiovascular, coronary, diabetes, hepatic, renal, or gastrointestinal diseases, traumas of the arms or hand, fingers, atopic dermatitis, thyroid disturbance, depression, anxiety, palpitations and chronic backache
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. Vegetarian, vegan or macrobiotic

Date of first enrolment
01/05/2013

Date of final enrolment
01/05/2014

Locations

Countries of recruitment
Italy

Study participating centre
University of Milan
Milan
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20133

Sponsor information

Organisation
University of Milan (Università degli Studi di Milano) (Italy)

Sponsor details
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Sponsor type
University/education

ROR
https://ror.org/00wjc7c48

Funder(s)

Funder type
Research organisation

Funder Name
The Cariplo Foundation, Milano (Italy) - research grants (2007-5810; 2010-2303) and intramural funding

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		01/03/2016	10/05/2021	Yes	No