ISRCTN27687092 https://doi.org/10.1186/ISRCTN27687092

Effects of black tea with and without a fat load on vascular function in mildly hypertensive volunteers

Submission date
11/03/2014

Recruitment status
No longer recruiting

Registration date
20/05/2014

Overall study status
Completed

Last Edited
03/04/2019

Condition category
Circulatory System

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

Plain English Summary
Background and study aims
Fruit, vegetables, red wine, cocoa and tea have been found to be very high in flavonoids. Flavonoid consumption may help to prevent heart disease. Therefore, we aimed to investigate the effects of regular consumption of black tea, which is naturally high in flavonoids, on some parameters of arterial function, including blood pressure.

Who can participate?
Never-treated essential hypertensive (EH) patients aged between 18 and 75 referred to our outpatient unit Centre of Hypertension and Cardiovascular Prevention of LAquila.

What does the study involve?
Participants were randomly allocated to consume either black tea or a placebo (dummy) drink twice a day for 8 days. After a 13-day break the participants then swapped over and consumed the other drink twice a day for 8 days. Participants were asked to maintain their normal diet and lifestyle during the study but to avoid consumption of tea, red wine, chocolate-based products, dietary supplements and aspirin. Vascular function and blood pressure was assessed before and after consumption of the test drink on day 7 and day 8 of each of the two phases. On day 7 all measurements were performed while participants were in a fasted state, while on day 8 participants also consumed whipping cream about 30 minutes after consuming the test drink.

What are the possible benefits and risks of participating?
Regular consumption of black tea, possibly due to its flavonoids, may help protect against heart disease. There were no risks involved in this study.

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

When is the study starting and how long is it expected to run for?
The study was conducted between March 2008 and March 2011.

Who is funding the study?
Unilever R&D (Netherlands).

Who is the main contact?
Davide Grassi
davide.grassi @cc.univaq.it

Contact information

Type(s)
Scientific

Contact name
Dr Davide Grassi

Contact details
University of LAquila
Department of Life, Health, and Environmental Sciences
Viale S Salvatore, Delta
6 Medicina
L'Aquila
Italy
67100

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Black tea lowers blood pressure and wave reflections in fasted and postprandial conditions in hypertensive patients: a randomized double-blind controlled cross-over trial

Study hypothesis
Hypertension is the leading risk factor for cardiovascular morbidity and mortality. Increased peripheral resistance due primarily to changes in vascular structure and function appear to be the fundamental hemodynamic abnormality in hypertension. These changes include endothelial dysfunction, arterial wall thickening and abnormal vascular tone, and are due to alterations in the biology of the arterial wall. Accordingly, an increased arterial stiffness is related to haemodynamic modifications at the level of the aorta, leading to a rise in cardiac afterload, a reduction in coronary perfusion and an over-stretch of the aortic wall. Epidemiological studies have shown an inverse association between diets rich in flavonoids and cardiovascular disease as

well as on specific flavonoid intake and vascular function. In this context, tea products account for a significant proportion of total flavonoid intake in different Western countries. A meal rich in fat has been reported to negatively affect blood pressure (BP) and vascular function. As most of the day is spent in the postprandial state, it is of interest to determine whether a fat-rich meal affects the postprandial BP and arterial haemodynamics. Furthermore, we hypothesized that treatment with black tea could protect vascular responses and lipemia-induced impairment of arterial function.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of LAquila, 20/12/2007, ref: 53/2007

Study design
Randomized double-blind controlled cross-over trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

Condition
Hypertension and arterial stiffness

Interventions
After a 7-day run-in period, participants were randomly assigned to consume a hot beverage containing 150 mg tea polyphenols (equivalent to 129 mg flavonoids) or placebo twice a day for 8 days in a double-blind cross-over design. Wash-out between the two treatments was 13 days. During these periods subjects were asked to maintain their normal diet and lifestyle avoiding consumption of tea, red wine, chocolate-based products, dietary supplements or aspirin. Vascular function and blood pressure were assessed prior to (baseline) and after consumption of the test beverage on day 7 and day 8 of each of the two intervention phases. On day 7 all measurements were performed in a fasted state before (t=0) and 1, 2, 3 and 4 h after consumption of the tea in a supine position in a quiet, temperature-controlled (22° to 24°C) room by trained, certified staff, who were blind about the study protocol. This procedure was repeated on day 8, but volunteers also consumed a fat load (ultra-heat-treated whipping cream: 1 g fat per kg bodyweight; for 100 ml of product: fats 27 g, carbohydrates 12.6 g, proteins 2.1 g; energy value 302 kcal) approximately 30 minutes after consuming the test product. Patients did not present any pain during the measures.

Composition of the test products (black tea) (mg per dose):
Polyphenols: Placebo: 0, Active: 150
Total caffeine: Placebo: 37.3, Active: 37.3
Tea solids: Placebo: -, Active: 497.5
Caffeine added: Placebo: 37.3, Active: -
Caramel colour: Placebo: 90, Active: -
Tea flavour: Placebo: 10, Active: -
Sugar (sucrose): Placebo: 1362.7, Active: 1402.5

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Flow-mediated dilatation of the brachial artery of the dominant arm was measured by ultrasonography with a non-invasive probe at approximately 5-10 cm above the elbow. After a 1-minute baseline measurement a cuff placed at the forearm just below the elbow will be inflated at 250 mmHg for 5 minutes and then deflated and the maximal dilation of the brachial artery will be measured.
2. Digital volume pulse measurements were evaluated by a validated finger photoplethysmographic device (a little clip on the finger). Three consecutive recordings were obtained in the index finger of the non-dominant hand with participants resting 15 min in supine position.
3. Office blood pressure measurements were recorded by a validated oscillometric device with appropriately sized cuffs (Omron 705 CP; Omron Matsusaka Co. Ltd., Matsusaka-City, Japan) on the dominant upper arm. For this purpose, patients rested 15 min in supine position. Then, the first blood pressure measurement was discarded and the subsequent three consecutive BP readings, taken at 5-min intervals, were recorded. The average of these latter measures was considered for statistical analysis.

All outcomes were measured on day 7 and day 8 of each of the two intervention phases.

Secondary outcome measures
1. In all individuals, a routine hematochemical check was performed by standard methods after each active treatment phase. Plasma glucose and insulin, serum total cholesterol, high-density lipoprotein (HDL) cholesterol, low-density lipoprotein (LDL) cholesterol, and triglyceride levels were assessed in the clinical chemistry laboratory using routine procedures. Plasma glucose and insulin values were used to calculate the index of insulin resistance, homeostasis model assessment of insulin resistance (HOMA-IR).
2. Further, blood samples were collected for clinical chemical analyses of vascular function and inflammation (endothelial activation): C-reactive protein, E-selectin, ICAM-1, Endothelin-1 and VCAM-1 levels (immuno-enzymatic methods - ELISA kits), including assessment of the number of circulating endothelial progenitor cells (counted manually in 10 randomly selected microscopic fields by two independent investigators with an inverted fluorescence microscope, after some laboratory phases).

All outcomes were measured on day 7 and day 8 of each of the two intervention phases.

Overall study start date

01/03/2008

Overall study end date
01/03/2011

Eligibility

Participant inclusion criteria
1. Never-treated essential hypertensive (EH) patients referred to the outpatient unit Centre of Hypertension and Cardiovascular Prevention of LAquila
2. ≥ 18 and ≤ 75 years of age
3. Non-diabetic
4. SBP between 140 and 159 mmHg or DBP between 90 and 99 mmHg
5. Body mass index between 19 and 31 kg/m2

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
20

Participant exclusion criteria
1. Being an employee of the Department of Internal Medicine and Public Health of the University of L'Aguila
2. Except for grade I hypertension no additional cardiovascular risk factors (including a recorded history of coronary infarction, vascular surgery, transient ischemic attack, left ventricular hypertrophy or cardiac arrhythmia or apparent family history of cardiovascular diseases)
3. A recorded history or current metabolic diseases, chronic gastrointestinal disorders, cardiovascular or renal disease or diabetes mellitus
4. Indications for compromised liver or kidney function.
5. Currently on a medically prescribed diet or slimming diet
6. Subjects with irregular pulse or pulse ≤50 or ≥100 bpm
7. Reported intense sporting activities > 10 hours/week
8. Subjects who are taking prescribed medical treatment that is likely to affect blood pressure (or who have been taking such medication in the past)
9. Use of systemic antibiotics in the period of 3 months prior to the study
10. Recent blood donation i.e. 1 month (male subjects) or 2 months (females) prior to the study and no planned blood donation during the study period
11. Reported intolerance or allergy to constituents of the study products
12. Reported lactating, pregnant or wishing to become pregnant during the study
13. Reported weight change ± 10% during a period of 6 months prior to the study

14. Reported participation in another biomedical study 3 months before the start or during the study
15. Reported smoking during a period of one year prior to the study or planning to smoke during the study
16. Reported participation in night shift work
17. Female participants not in post-menopausal phase

Recruitment start date
01/03/2008

Recruitment end date
01/03/2011

Locations

Countries of recruitment
Italy

Study participating centre
University of LAquila
L'Aquila
Italy
67100

Sponsor information

Organisation
Unilever Food and Health Research Institute (UFHRI) (Netherlands)

Sponsor details
Olivier van Noortlaan 120
Vlaardingen
Netherlands
3133

Sponsor type
Industry

ROR
https://ror.org/02436cs38

Funder(s)

Funder type
Industry

Funder Name
Unilever R&D (Netherlands)

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	04/02/2015		Yes	No