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Effects of upper body exercise training and beetroot juice on blood pressure

Submission date
11/12/2013

Recruitment status
No longer recruiting

Registration date
16/01/2014

Overall study status
Completed

Last Edited
13/03/2020

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Physical activity and inorganic nitrate have both been associated with a reduction in blood pressure (BP) and improvement in arterial health. Physical activity interventions based on training of the upper arms have provided initial support for a beneficial effect on blood pressure. Similarly, inorganic nitrate supplementation given in water, as a tablet or as fruit juice (beetroot) was associated with a decrease in blood pressure. However, the effects of the two interventions have never been compared and most importantly no data is available on the effects of upper arm exercise training and beetroot juice on blood pressure in older overweight and obese subjects.
The aim of the study is thus to find out about the effects of handgrip training and beetroot juice on blood pressure and arterial health in overweight and obese older subjects.

Who can participate?
Overweight men or women between the ages of 55 and 70 years.

What does the study involve?
Participants will be randomly allocated to one of three groups:
A low nitrate diet plus beetroot juice consumption for 7 days
A low nitrate diet plus handgrip training for 7 days
A low nitrate diet for 7 days
Each participant will be given specific dietary instructions to control the content of nitrate in their diet. Measurements of blood pressure and arterial health will be performed at the start and at the end of the study.

What are the possible benefits and risks of participating?
All the laboratory procedures involved in this study are simple to perform and involve minimal risks to participants. Blood sampling, for example, is a routine procedure. Although there might be a risk for a small bruise, this will be minimised by the fact that the staff undertaking these are widely experienced.
The amount of nitrate intake (provided as beetroot juice) to be used in this study is commonly observed in subjects with a high intake of fruit and vegetables (particularly leafy vegetables) and it is significantly lower than the nitrate intake that may be observed in vegetarian subjects.

There is no established health risk associated with either this level of nitrate intake or with beetroot juice supplementation. The consumption of beetroot juice can be associated in a small number of subjects (<15% of the population) with a red or pink urine or faeces colour. This is related to a particular pigment present in beetroot (betalain). Participants will be explained that this has no effect on their health. At the screening visit participants will be asked whether they have an dislike for beetroot or beetroot juice and they will be excluded if they report a problem with the consumption of these products.
The exercise involves minimal effort and is customised to individual needs. However, we will exclude subjects with established cardiovascular diseases such as heart failure, angina or myocardial infarction.
In this study we will screen participants for hypertension and obesity and therefore participants and, with their consent, their GPs will be informed of these screening results. Although there is no anticipated direct benefit to participants of this study, some participants might have an interest in learning about their health and nutritional status; others see a benefit in volunteering to research studies and thus contributing to scientific advances.

Where is the study run from?
The study is run at the Clinical Ageing Research Unit, Newcastle University (UK).

When is the study starting and how long is it expected to run for?
The study started in June 2012. Recruitment will continue until 36 subjects are enrolled.

Who is funding the study?
Human Nutrition Research Centre, Institute for Ageing and Health, Newcastle University (UK).

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Effects of isometric exercise and inorganic nitrate consumption on cardiovascular function in overweight and obese subjects

Study objectives
We hypothesise that isometric exercise and nitrate supplementation reduce blood pressure (BP) in older healthy people. The mechanisms underlying the BP drop could be linked to a greater insulin sensitivity and vascular compliance and to an increase in nitric oxide (NO) bioavailability in the exercise and nitrate groups, respectively.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The National Research Ethics Committe services (NRES) Committee North East - Northern & Yorkshire, 23/04/2012, Ref:12/NE/0134

Study design
Single-center non-blinded randomised controlled trial with three parallel arms

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

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

Effect of beetroot juice and handgrip training on blood pressure in older adults who are overweight or obese

Interventions

Random allocation (beetroot juice, handgrip strength or control).
1. A low nitrate diet plus beetroot juice consumption for 7 days
2. A low nitrate diet plus handgrip training for 7 days
3. A low nitrate diet for 7 days (control)

Participants are encouraged to consume food in the habitual amount; however, they are recommended to avoid high nitrate foods for which they receive advice on what to avoid. The energy content of the beetroot juice is 173 kcal. The interventions lasts for 7 days.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. 24-hour blood pressure
2. Endothelial function

The outcome measures will be evaluated at days 0 and 8 (i.e. before and after 7 days intervention). The primary outcome measure is ambulatory 24-hour blood pressure, which will be evaluated on days 0 and 8.

Secondary outcome measures

1. To compare the effects of handgrip training and beetroot juice on muscle strength
2. To assess the association between arterial health, body fat and memory performance
3. To test the relationship between handgrip training and beetroot juice with clinical risk factors for diabetes (insulin, glucose) and high blood pressure

Arterial distensibility, which will be undertaken in a temperature-controlled measurement room (~23 ± 1 degrees Celsius). Each subject will be invited to lie supine for a 5-min rest period. Optical probes will then be attached to the right index fingertip and right earlobe, and a long cuff will be wrapped around the whole right arm. Single-lead ECG will be also recorded simultaneously. All the measurements will be performed by an experienced operator. A series of five separate measurements will be performed with different external cuff pressures (0, 10, 20, 30 and 40 mmHg) applied to the whole right arm through the long cuff, with a minute rest interval between each measurement. During the recording session, the arms will be kept parallel to the body and as still as possible, with regular and gentle breathing. The measurement will last approximately 30 minutes (Zheng D, Murray A. Peripheral arterial volume distensibility: Significant differences with age and blood pressure measured using an applied external pressure. Physiol Meas. 2011;32:499-512).

Handgrip strength: handgrip strength will be assessed in both arms at baseline and after the intervention to measure the maximum isometric strength of the hand and forearm muscles. A lightweight and portable dynamometer will be used. The researcher will follow a specific protocol for the measurement of handgrip strength (i.e. allowing one practice trial, and then record the best of three attempts with 30 seconds rest between each of these).

Overall study start date
01/06/2012

Completion date
02/02/2014

Eligibility

Key inclusion criteria
1. Healthy (with no established diagnosis)
2. Non-smoking men and women aged 55-70 years with a body mass index (BMI) in the range of 25-40 kg/m2.

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
36

Key exclusion criteria
1. Current participation in other clinical investigations.
2. Physical disabilities, trauma or surgery which limit mobility and impede physical performance (i.e. not able to comply with the isometric exercise intervention).
3. Vegetarianism (likely to have very high nitrate intake).
4. Aversion to beetroot consumption or inability to comply with the study diet (lack of compliance).
5. High physical activity level (may have BMI in obese range but low fat mass).
6. Weight change more than 3.0 kg in the last 2 months (important influence on systemic metabolism and vascular function).
7. Active cancer and any diagnosis of malignant cancer in the last 5 years (systemic effects on study outcomes).
8. Chronic and acute metabolic and inflammatory conditions interfering with the study outcome (systemic effects on study outcomes). For example, severe hypertension (>180 mmHg/>110), kidney stones, gallstones, skin rashes or rheumatoid arthritis.
9. Previous diagnosis of type 1 or type 2 diabetes treated with insulin and oral hypoglycaemic agents (modification of regulation of intermediate metabolism).
10. Weight loss medications (sibutramine, orlistat, rimonabant) and history of bariatric surgery (weight loss related changes in systemic metabolism).
11. Drugs: corticosteroids, sildenafil, diuretics, laxatives, anticoagulants, antacids, nitrate-derived agents, anti-cholinergic, anti-hypertensive (beta-blockers, calcium antagonists, ACE inhibitors and angiotensin receptor inhibitors) (all drugs have either an effect on NO production or insulin sensitivity via different mechanisms).
12. Subjects on hormonal therapies (oestrogens, thyroxine, progesteron), statins and any other anti-dyslipidaemic agent and psychiatric drugs (antidepressants, sedatives, antipsychotics) will

be excluded if dose has been started/changed in the previous six months (make sure that these disorders are under strict control to avoid interference with the study outcomes)
13. Haematological disorders including severe anaemia (Hb < 10mg/dL) (risk for the participant and effects on the study outcomes)
14. Major surgical operations interfering with the study outcomes (systemic effects on study outcomes)
15. Alcohol intake >21 units/week for men and >14 units/week for women
16. Non English speakers or volunteers requiring translators or interpreters (since these services are not available for this study)

Date of first enrolment
01/06/2012

Date of final enrolment
02/02/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Research Associate
Newcastle on Tyne
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Sponsor information

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University/education

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ROR
https://ror.org/01kj2bm70

Funder(s)

Funder type
University/education

Funder Name
Human Nutrition Research Centre, Institute for Ageing and Health, Newcastle University (UK)

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	01/10/2015		Yes	No