ISRCTN13566025 https://doi.org/10.1186/ISRCTN13566025

Impact of moderate intensive physical activity on bioavailability of flavanones in sedentary females

Submission date
27/06/2016

Recruitment status
No longer recruiting

Registration date
10/08/2016

Overall study status
Completed

Last Edited
10/08/2016

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Citrus fruits and their juices, especially orange juice (OJ), are a common source of polyphenols (compounds found in plants), particularly flavanones (a plant pigment that protects against degenerative diseases such as cancer and heart disease) subcategory.
The health benefits associated with flavanone consumption are likely to be related to their bioavailability (how well they are absorbed into the blood stream) rather than the amount consumed. Limited evidence suggests that bioavailability of orange juice flavanones is increased in individuals who practice endurance-training exercise. This suggests that enhancing physical activity should lead to an enhancement of the bioavailability of flavanones of in previously physically inactive (sedentary) individuals. The aim of this study is to investigate how well flavanones are absorbed by the body following consumption of orange juice is influenced by four weeks of endurance training.

Who can participate?
Healthy women over the age of 18 who have had a sedentary lifestyle for at least six weeks.

What does the study involve?
All participants take part in two experimental tasks, before and after the four week exercise program. The exercise program itself consists of endurance train (either cycling, running or both) for 30 minutes in week one, 40 minutes in week two, 50 minutes in week three and 60 minutes in week four, at the Exercise and Energy Balance Laboratory at the University of Glasgow. During the experimental tasks, participants are asked to come to the study centre in the morning after not having eaten or drunk anything for 12 hours, bringing a sample of urine from overnight. A sample of blood is then taken, before the participants drink 500ml freshly squeezed orange juice. Further blood samples are taken hourly for eight hours after drinking the juice. Four hours after drinking the juice, participants are given a white roll with butter and some cheese and at the end of the experimental test with a polyphenol-free dinner. Participants are then able to go home, but are instructed to avoid polyphenol containing foods during the rest of the day and record all food and drink consumed. Participants are also asked to collect samples of urine 0–2, 2–5, 5-8, 8-10, 10–20, 20-24 hours after drinking the juice, which are delivered to the study

centre the next day, when a final blood sample is taken. The blood and urine samples are then tested in the laboratory for levels of flavanone breakdown products.

What are the possible benefits and risks of participating?
Participants may benefit from gaining insight in the research process and learning about their health status, as well as receiving a financial reward for taking part. There is a small risk of pain, bruising or infection (very rare) following blood samples being taken.

Where is the study run from?
University of Glasgow (UK)

When is the study starting and how long is it expected to run for?
August 2014 to September 2016

Who is funding the study?
University of Glasgow (UK)

Who is the main contact?
Dr Dalia Malkova

Contact information

Type(s)
Scientific

Contact name
Dr Dalia Malkova

ORCID ID
http://orcid.org/0000-0002-8085-0528

Contact details
School of Medicine, Nursing and Dentistry
College of Medical, Veterinary & Life Sciences
University of Glasgow
Room 3.87, Level 3
New Lister Building Glasgow Royal Infirmary
10-16 Alexandra Parade
Glasgow
United Kingdom
G31 2ER

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

M-120

Study information

Scientific Title
The effect of a four week exercise intervention on bioavailability of orange juice flavanones in healthy sedentary females

Study objectives
Bioavailability of orange juice flavanones in sedentary females can be enhanced by participation in aerobic exercise programmes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Glasgow, MVLS Ethics Committee, 05/11/2014, ref: 200140020

Study design
Single-centre non randomised study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Bioavailability of orange juice flavanones

Interventions
Participants will conduct two 24 hour orange juice feeding trials, one before and another after 4 weeks of moderate intensity exercise intervention.

Exercise intervention will involve endurance exercise (cycling, running or combination of both) for 30 minutes in week 1, 40 minutes in week 2, 50 minutes in week 3 and 60 minutes in week 4. The work load of cycling and running speed will be set up at 70-80% of the predicted maximal heart rate. All training sessions will take place at Exercise and Energy Balance Laboratory (New Lister Building, University of Glasgow, Glasgow, UK) and be supervised by a researcher.

During the feeding trials, urine and blood samples will be collected at regular intervals for the duration of 24 hours after consumption of 500 ml of orange juice. From this, urinary polyphenol metabolites and catabolites will be measured and analysed qualitatively and quantitatively. On the morning of the orange juice feeding trials, participants will report to the metabolic laboratory between 0800 and 0900 hours after a 12 hour fast and bring their excreted overnight urine sample. Body mass and body fat will be measured, before participants consume 500 mL of orange juice (Tropicana, Tesco). Four hours after beginning of the trial participants will be provided with a white roll with butter. After 8 hours, participants will be provided with a standard low (poly)phenol meal after which they will leave the laboratory to sleep at home. They will be instructed to continue the low (poly)phenol diet that evening and return to the laboratory the next morning to provide overnight urine and fasting blood sample. During the feeding trials participants will collect all urine excreted over the following time periods after drinking the orange juice: 0-2, 2-5, 5-8, 8-10 and 10-24 hours. Urine will be collected into sealable flasks and kept on ice. The total volume of each urine fraction will be recorded and 2 mL aliquots will be stored stored at –80°C prior to analysis.

Intervention Type
Behavioural

Primary outcome measure
Concentration of naringenin and hesperetin metabolites and phenolic acids in urinary fractions collected overnight (0 hours) and after ingestion of orange juice (0-2, 2-5, 5-8, 8-10, 10-24 hours) is measured before and after 4 week exercise intervention by using HPLC-PDA-MS and GC-MS.

Secondary outcome measures
1. Concentration of naringenin and hesperetin metabolites and phenolic acids in plasma collected overnight (0 hours) and at 1, 2, 3, 4, 5, 6, 7, 8, 24 h after the juice intake is measured before and after 4 week exercise intervention by using HPLC-PDA-MS and GC-MS
2. Flavanones in orange juice (Tropicana, Tesco) used for 24 hour feeding trials are measured using HPLC-PDA-MS
3. Mouth to caecum transit time is breath samples collected in the fasted state (0 hours) and at 30 minute intervals for 8 hours after the juice intake is measured before and after 4 week exercise intervention by using a breath hydrogen monitor
4. Body weight is measured in the fasted state in kilograms before and after 4 week exercise intervention using Tanita TBF-410GS Body Composition Analyzer
5. Body fat percentage is measured in the fasted state before and after 4 week exercise intervention using Tanita TBF-410GS Body Composition Analyzer
6. Waist circumference in centimetres is measured in the fasted state before and after 4 week exercise intervention using a measuring tape for circumferences
7. Blood pressure and heart rate is measured in the fasted state before and after 4 week exercise intervention using Omron 7051T blood pressure monitor
8. Ferric reducing ability of plasma (FRAP) in plasma collected in the fasted state (0minutes) and at 1, 2, 3, 4, 5, 6, 7, 8, 24 hours after the juice intake is measured before and after 4 week exercise intervention by using Automated FRAP assay
9. Plasma biomarkers of inflammation such as C-reactive protein (CRP), interleukin-6 (IL-6), and tumor necrosis factor-alpha (TNF-alpha) in plasma collected in the fasted state (0minutes) and at 1, 2, 3, 4, 5, 6, 7, 8, 24 hours after the juice intake is measured before and after 4 week exercise intervention by using commercially available ELISA kits

Overall study start date

01/08/2014

Completion date
10/09/2016

Eligibility

Key inclusion criteria
1. Sedentary status for at least 6 weeks
2. Healthy
3. BMI over 30
4. Normotensive
5. Non-smoker
6. Not taking any drug therapies
7. Aged 18 years and over

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
22

Key exclusion criteria
1. History of gastrointestinal disease
2. Vegetarian
3. Unstable food habits
4. Pregnancy

Date of first enrolment
05/11/2014

Date of final enrolment
30/08/2016

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
University of Glasgow
Exercise and Energy Balance Laboratory (Room 3.10)
New Lister Building
Glasgow Royal Infirmary
School of Medicine, Dentistry and Nursing
College of Medical, Veterinary and Life Sciences
Alexandra Parade
Glasgow
United Kingdom
G31 2ER

Sponsor information

Organisation
University of Glasgow

Sponsor details
University Avenue
Glasgow
Scotland
United Kingdom
G12 8QQ

Sponsor type
University/education

ROR
https://ror.org/00vtgdb53

Funder(s)

Funder type
University/education

Funder Name
University of Glasgow

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication of at least two papers in in scientific/ general medical journals, and presentation at relevant meetings.

Intention to publish date
10/09/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		07/07/2016	10/08/2016	No	Yes