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Absorption of orange juice polyphenols

Submission date
03/07/2014

Recruitment status
No longer recruiting

Registration date
23/07/2014

Overall study status
Completed

Last Edited
24/02/2015

Condition category
Other

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

Plain English summary of protocol

Background and study aims
Oranges are one of the most popular foods in the world and are commonly enjoyed as a fresh fruit and as a juice. They are a great source of many nutrients including polyphenolic compounds called flavanones. There is evidence to suggest that flavanones may be, in part, responsible for a potentially protective effect of orange juice against cardiovascular (heart) disease. Flavanones, like antioxidants, 'mop up' free radicals, molecules that damage blood vessels and cause arteries to become clogged up with cholesterol. Once drunk, the flavanones in orange juice are broken down into metabolites in the digestive system before they are then taken into the blood stream. It is, therefore, the effects of these metabolites that lead to the protective effects against cardiovascular disease (CD). The eventual aim is to understand how these metabolites work in the body, but here we are working towards identifying and quantifying those that are produced in the digestive system (namely the gastrointestinal tract) before they enter the bloodstream. In our previous work, we have looked at the appearance of flavonone metabolites in the blood after the drinking of some orange juice. This study will look at their excretion (removal from the body) in the urine 0-24 hours after the drinking of orange juice as this gives us a much better overall measure of how much has been absorbed.

Who can participate?
Healthy volunteers between 20 and 60 years old, non-smokers and not under medication.

What does the study involve?
Volunteers are required to follow a diet low in polyphenolic compounds for 48 hours before the start of the study and for 24 hours after supplementation, avoiding fruits, vegetables, high-fibre products, and drinks such as tea, coffee, fruit juice, and wine. Then, after an overnight fast, each person drinks 250 mL of pulp-enriched orange juice. A light breakfast of white bread, cheese, ham and milk is provided 2 hours after the orange juice has been drunk. Two weeks later, the volunteers drink 250 mL of a placebo drink. All urine is collected on five occasions over the periods 0, 0-2, 2-5, 5-10 and 10-24 hours after drinking either the orange juice or placebo drink.

What are the possible benefits and risks of participating?
There are no potential risks or benefits to taking part in the study.

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

When is the study starting and how long is it expected to run for?
January 2012 to December 2012

Who is funding the study?
The Coca-Cola Company (USA)

Who is the main contact?
Professor Mike Lean
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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
2011017

Study information

Scientific Title
Bioavailabilty of Orange Juice polyphenols: a cross-over, non-randomised intervention

Acronym
BOJ

Study objectives
Including the detection and quantification of flavanone metabolites and their colonic microflora-mediated breakdown products in the investigation of orange juice polyphenol absorption and metabolism will lead to a better understanding of their real bioavailability in humans.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Glasgow, MVLS College Ethics Committee, 21/12/2011, Project Number: 2011017

Study design
Cross-over non-randomised intervention

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Other

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
Bioavailabilty of orange juice polyphenols

Interventions
Each subject will drink 250 ml of pulp-enriched orange juice. A light breakfast consisting of white bread, cheese, ham and milk will be provided 2 h after orange juice intake. After a wash-out period of 2 weeks, the volunteers will ingest 250 ml of a placebo drink. Following supplementation, all urine will be collected over five time periods (0, 0-2, 2-5, 5-10 and 10-24 hours).

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The absolute bioavailability of orange juice phenolics will be the primary outcome of this study. Polyphenol metabolites and catabolites will be identified and quantified in urine collected over five time periods (0, 0-2, 2-5, 5-10 and 10-24 hours) following supplementation, using high-

performance liquid chromatography coupled with tandem mass spectrometry and gas chromatography coupled with mass spectrometry.

Secondary outcome measures
N/A

Overall study start date
03/01/2012

Completion date
01/12/2012

Eligibility

Key inclusion criteria
1. Healthy men and women.
2. Age 20-65 years

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
12

Key exclusion criteria
1. Smoking
2. On no medication

Date of first enrolment
03/01/2012

Date of final enrolment
01/12/2012

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre

Glasgow Royal Infirmary
Glasgow
United Kingdom
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Sponsor information

Organisation
The Coca-Cola Company (USA)

Sponsor details
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Sponsor type
Industry

Website
http://us.coca-cola.com

ROR
https://ror.org/00yc8qw13

Funder(s)

Funder type
Industry

Funder Name
The Coca-Cola Company (USA)

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	01/11/2014		Yes	No