

# Absorption of orange juice polyphenols

<b>Submission date</b> 03/07/2014	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 23/07/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 24/02/2015	<b>Condition category</b> Other	<input type="checkbox"/> 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  
Mike.Lean@glasgow.ac.uk

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Mike Lean

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## Additional identifiers

**Protocol serial number**  
2011017

## Study information

**Scientific Title**  
Bioavailability 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

**Study type(s)**

Other

**Health condition(s) or problem(s) studied**

Bioavailability 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(s)**

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.

**Key secondary outcome(s)**

N/A

**Completion date**

01/12/2012

**Eligibility****Key inclusion criteria**

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

**Participant type(s)**

Healthy volunteer

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**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**

United Kingdom

Scotland

**Study participating centre**

Glasgow Royal Infirmary

Glasgow

United Kingdom

G31 2ER

**Sponsor information****Organisation**

The Coca-Cola Company (USA)

**ROR**

<https://ror.org/00yc8qw13>

# Funder(s)

## Funder type

Industry

## Funder Name

The Coca-Cola Company (USA)

# Results and Publications

## 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?
<a href="#">Results article</a>	results	01/11/2014		Yes	No