

# Furanocoumarin metabolites as dietary biomarkers of grapefruit consumption

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<b>Registration date</b> 13/05/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 13/05/2014	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Grapefruit contains high amounts of furanocoumarins, a group of compounds that are known to reduce the activity of intestinal enzymes. As a result, grapefruit juice can interact with a variety of drugs that are taken orally. The aim of this study is to find out whether the breakdown products of furanocoumarin can be used as markers of grapefruit juice consumption.

### Who can participate?

Healthy men aged 20-35 years.

### What does the study involve?

Participants will be randomly allocated to drink 250 mL of either orange, lemon or grapefruit juice at dinner time. There will then be a 7-day break in which participants are requested to avoid consuming citric-based products. Participants will then repeat this process twice with the second and third juices. Urine samples will be collected the day before the first intervention and in the morning following each intervention.

### What are the possible benefits and risks of participating?

The study was conducted according to the Declaration of Helsinki of the World Medical Association. The study was explained to subjects through verbal and written instructions, and written informed consent was obtained before participation.

### Where is the study run from?

This study involved the Department of Nutrition and Food Science of the University of Barcelona (Spain).

### When is the study starting and how long is it expected to run for?

This study will take place between May 2013 and March 2014.

### Who is funding the study?

This study is supported by CIBERobn.

Who is the main contact?  
Dr Rosa Lamuela-Raventós  
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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**  
Targeted metabolomics approach for the determination of furanocoumarin metabolites in urine after grapefruit juice consumption

**Study objectives**  
Grapefruit contains considerable amounts of furanocoumarins, a family of compounds which are known to strongly inhibit intestinal cytochrome P450 (CYP) enzymes, namely CYP3A4. As a result, grapefruit juice can interact with a variety of orally administered drugs by increasing their bioavailability. This study aims to study the potential of furanocoumarin metabolites as specific biomarkers of grapefruit juice consumption.

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**

Ethics Committee of Clinical Investigation of the University of Barcelona (Spain), 18/12/2014, ref: IRB00003099

**Study design**

Open controlled clinical trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**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**

Concentration of furanocoumarin metabolites in urine

**Interventions**

Participants are randomly assigned following simple randomization procedures (computerized random numbers) to one of three treatment groups. The study is a randomized crossover feeding trial. Participants will cross over and undergo all three of the interventions.

Intervention 1: Administration of 250 mL orange juice.

Intervention 2: Administration of 250 mL lemon juice.

Intervention 3: Administration of 250 mL grapefruit juice

Before each intervention, participants will follow a 7-day washout period, avoiding consuming citric or citric-based products

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

Furanocoumarin metabolites will be identified through liquid chromatography coupled to Orbitrap mass spectrometry. Concentrations of furanocoumarins will be determined by liquid chromatography coupled to tandem mass spectrometry (LCMS/MS). These determinations will be carried out in first morning urine samples collected the day before the first intervention and in the morning following each intervention.

**Secondary outcome measures**

N/A

**Overall study start date**

01/05/2013

**Completion date**

01/04/2014

## **Eligibility**

**Key inclusion criteria**

Healthy adult males aged 20-35 years

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Male

**Target number of participants**

15

**Key exclusion criteria**

1. Previous history of cardiovascular disease (ischemic heart disease - angina or recent or old myocardial infarction, cerebral vascular accident, or peripheral vascular disease)
2. Homeostatic disorders
3. Any several chronic diseases
4. Hypertension or dyslipidemia
5. Smoking subjects
6. Alcoholism
7. Other toxic abuse

**Date of first enrolment**

01/05/2013

**Date of final enrolment**

01/04/2014

## **Locations**

**Countries of recruitment**

Spain

**Study participating centre**  
**Nutrition and Food Science Department**  
Barcelona  
Spain  
08028

## **Sponsor information**

### **Organisation**

Centros de Investigación Biomédica en Red Fisiopatología de la Obesidad y la Nutrición (CIBERObn) (Spain)

### **Sponsor details**

Centro Hospitalario Universitario de Santiago de Compostela  
Edificio "D" 1ª  
Planata  
Choupana, S/N  
Santiago de Compostela  
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### **Sponsor type**

Research organisation

### **Website**

<http://www.ciberobn.es/>

### **ROR**

<https://ror.org/02s65tk16>

## **Funder(s)**

### **Funder type**

Research organisation

### **Funder Name**

Centros de Investigación Biomédica en Red Fisiopatología de la Obesidad y la Nutrición (Centers of Biomedical Research Network Pathophysiology of Obesity and Nutrition) (CIBERObn) (Spain)

## **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