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Furanocoumarin metabolites as dietary biomarkers of grapefruit consumption

Submission date
07/02/2014

Recruitment status
No longer recruiting

Registration date
13/05/2014

Overall study status
Completed

Last Edited
13/05/2014

Condition category
Other

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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?
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Contact information

Type(s)
Scientific

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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

Primary study design
Interventional

Study design

Open controlled clinical trial

Study type(s)
Other

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(s)
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.

Key secondary outcome(s)
N/A

Completion date
01/04/2014

Eligibility

Key inclusion criteria
Healthy adult males aged 20-35 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Male

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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration