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Does eating oranges reduce inflammatory and other risk markers related to cardiovascular diseases?

Submission date	Recruitment status	[_] Prospectively registered
30/06/2018	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
13/08/2018	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
04/10/2022	Circulatory System	

Plain English summary of protocol

Background and study aims
The aim of this study is to analyze the effects of the consumption of oranges on cardiovascular risk biomarkers (biological molecules found in the blood, other body fluids, or tissues that are a sign of heart disease).

Who can participate?
Healthy men and women

What does the study involve?
After a minimum of 8 hours fasting participants are randomly allocated to eat 500 g of peeled oranges or an isocaloric (same energy as the oranges) solution of sucrose in water. No other food is allowed for 4 hours. At the start and after 4 hours blood and urine samples are taken as well as blood pressure and body measurements and questionnaire data. Biomarkers are measured in the blood and urine samples. After a 1-week break the two groups swap over and the study is repeated. In a longer study with a subgroup of the initial volunteers, participants are randomly allocated to be told to either eat oranges every day for a month, or to reduce their intake of oranges for a month. At the start and after 1 month, samples of blood and urine are taken for biomarker measurements.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
University of Valencia (Spain)

When is the study starting and how long is it expected to run for?
April 2015 to December 2019

Who is funding the study?
University of Valencia (Spain)

Who is the main contact?
Prof. Dolores Corella

Contact information

Type(s)
Scientific

Contact name
Prof Dolores Corella

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
UV111

Study information

Scientific Title
Effects of the consumption of oranges on gene expression and other biomarkers of disease and intake in a healthy population in a randomized intervention trial

Acronym
ORANGOMICS

Study objectives
The short-term intake of oranges will have a favorable effect on biochemical markers related with cardiovascular risk, also including gene expression, metabolomic and epigenomic markers. As a secondary aim, metabolomic studies will provide a panel of markers for intake.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Review Board of Valencia University (human subjects), 26/03/2015, ref: H1425917369905

Study design
Cross-over randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Effect of eating oranges on cardiovascular disease biomarkers in healthy people

Interventions
For the short-term cross-over randomized trial. In a computer generated random order, 15 of the 30 study participants were assigned to the intervention with oranges. 500 g of peeled oranges were administered after a minimum of 8 h fasting. No other food was administered or ingested during 4 h. The other 15 subjects were the control arm and after a minimum of 8 h fasting received an isocaloric (same energy than the oranges) solution of sucrose in water. No other food was administered of ingested during 4 h. At baseline and after 4 h plasma, urine, serum and buffy coat samples were obtained as well as blood pressure, anthropometric and questionnaire data. The DNA and RNA are isolated. RNA is used for the study of gene expression and biomarkers are determined in plasma and urine samples, including metabolomic analyses. The wash-out period was 1 week and the interventions cross-over.

Subsequently, a longer intervention study is carried out with nutritional advice to increase the consumption of oranges in a subgroup of the initial volunteers. It is a parallel and randomized design of 1 month. Subjects were randomly allocated to two groups (oranges and control group) and the intervention arm consisted of the advice of eating oranges all days during a month. The control arm received advise of a reduced intake of oranges during a month. At baseline and monthly, biological samples of plasma, urine, serum and buffy coat are also taken for subsequent measurements. It is analyzed if the consumption of oranges has a favorable effect on these markers.

In parallel, a metabolomic study is proposed to identify markers of the intake of oranges since the short-term intervention study provides a unique intervention with this food. The subsequent longer-term study along with other foods in the diet will also allow validation of the use of metabolomic markers for consumption of oranges and secondary analyses of metabolomic biomarkers of other foods.

Intervention Type
Behavioural

Primary outcome measure
Classical biochemical parameters related to cardiovascular risk at baseline and 4 h/1 month, also including novel omics markers (in plasma and/or urine) analyzed by metabolomics (also including markers of intake), gene expression and other omics

Secondary outcome measures
For the short-term crossover intervention trial, measured at baseline and 4 h:
1. Blood pressure
2. Anthropometric variables (weight, height, waist circumference and body composition by bioimpedance)
3. Genetic polymorphisms
4. Food intake measured by a validated food frequency questionnaire
5. Taste perception tests with standardized tastants for bitter, sour, sweet, umami and salty

For the 1-month intervention, measured at baseline and 1 month:
1. Blood pressure
2. Anthropometric variables (weight, height, waist circumference and body composition by bioimpedance)
3. Genetic polymorphisms

Overall study start date
01/04/2015

Completion date
31/12/2019

Eligibility

Key inclusion criteria
Healthy men and women

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
30

Key exclusion criteria
1. Diseased
2. Allergic to oranges
3. Immunodeficiency or HIV-positive status
4. Liver cirrhosis or chronic renal failure
5. Serious psychiatric disorders: schizophrenia, bipolar disease, eating disorders, depression, etc
6. Any severe co-morbid condition

7. Alcohol abuse or addition
8. History of major organ transplantation
9. Concurrent therapy with immunosuppressive drugs or cytotoxic agents
10. Current treatment with systemic corticosteroids
11. Current use of weight loss medication
12. Patients with an acute infection or inflammation
13. Any other condition that may interfere with the completion of the study protocol

Date of first enrolment
05/04/2015

Date of final enrolment
05/05/2015

Locations

Countries of recruitment
Spain

Study participating centre
Universidad de Valencia
Avda. Blasco Ibanez, 13
Valencia
Spain
46010

Sponsor information

Organisation
Universitat de Valencia

Sponsor details
Avda. Blasco Ibanez, 13
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46010

Sponsor type
University/education

ROR
https://ror.org/043nxc105

Funder(s)

Funder type
University/education

Funder Name
Universitat de València

Alternative Name(s)
University of Valencia, 85|86

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Spain

Results and Publications

Publication and dissemination plan
Publication in international journals and scientific meetings.

Intention to publish date
15/09/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available as the patients did not provide informed content for sharing.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		29/06/2020	04/10/2022	Yes	No