

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

<b>Submission date</b> 30/06/2018	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 13/08/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 04/10/2022	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

## 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

**Contact details**  
Avda. Blasco Ibanez, 15  
Valencia  
Spain  
46010

## 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 or 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 advice 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

Valencia

Spain

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?
<a href="#">Results article</a>		29/06/2020	04/10/2022	Yes	No