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Does the consumption of oranges and Iberian cured-ham modify the expression of the genes related to obesity?

Submission date
21/12/2018

Recruitment status
No longer recruiting

Registration date
27/12/2018

Overall study status
Completed

Last Edited
16/08/2019

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Diet is one of the main factors related to gene expression and subsequently to obesity and cardiovascular risk depending of the gene expression profile. There are some genes for which a high level of expression is protective againts obesity or cardiovascular risk, and for other genes, an increased level of gene expression is detrimental. When analyzing a whole dietary pattern, it is difficult to separate the effect of the different foods on gene expression, therefore the analysis of the effects of the separate consumption of different foods is needed. Here, the aim of our study is to analyze the effects of the consumption of oranges on gene expression (at short term) as well as the effects of the consumption of Iberian cured-ham on gene expresion (at short term) in healthy subjects. After an initial screeenig of the whole transcriptome in a subsample, we will focus the analysis on genes related to obesity/cardiovascular risk. In addition we will examine the short term effect on plasma fasting glucose and triglycerides and we will collect plasma and urine samples to be stored for metabolomic analysis of markers of oranges and Iberian cured-ham intake.

Who can participate?
Healthy men and women from the general population (aged 18-50 years)

What does the study involve?
We will carry out a cross-over randomized trial in healhty volunteers. After a minimum of 10 hours fasting participants (30 subjects) are randomly allocated to eat 500 g of peeled oranges or 65-70 g of Iberian cured-ham. 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. General and lifestyle questionaries (diet, physical activity, sleep characteristics) will be adminstered at baseline. RNA will be isolated at baseline and at 4h of each intervention and changes in gene expression analyzed. Fasting glucose and triglycerides will be measured in plasma at baseline and at 4h by standard procedures. Plasma and urine samples both at baseline and at 4h will be collected and stored to further analyze metabolomic makers of oranges and cured-ham intake).

What are the possible benefits and risks of participating?
Participants will be informed that there are not benefits and risks expected.

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

When is the study starting and how long is it expected to run for?
December 2018 to July 2019

Who is funding the study?
BIOGENOME DX S.L. and the Univeristy of Valencia (Spain)

Who is the main contact?
Prof. José V. Sorlí

Contact information

Type(s)
Scientific

Contact name
Dr Jose V Sorli

Contact details
Avda Blasco Ibanez 15
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46010

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PCT2E_18

Study information

Scientific Title
Comparison of the effects of orange consumption versus Iberian cured-ham consumption as regulators of the expression of genes related to obesity in a randomized clinical trial

Acronym
OBORHAM

Study objectives

The short-term intake of oranges and the separate short-term intake of Iberian cured-ham will have an specific and differential effect on gene expression. In particular, each one of the interventions will have a particulareffect on the expression of genes realated to obesity /cardiovascular risk, and the comparison of both gene expression profiles will provide data regarding the most favorable intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional review board of Valencia University (human subjects), 14/12/2018, ref: H1544387178475

Study design
Interventional, randomised cross over trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Community

Study type(s)
Prevention

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

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

Interventions
This is short term cross-over randomized trial including 30 participants. Intervention will consist of the administration of selected food (oranges and Iberian cured-ham). For the short-term cross-over randomized trial. In a computer generated random order, 15 of the 30 study participants will be assigned to the intervention with oranges. 500 g of peeled oranges will be administered after a minimum of 10 hours fasting. No other food will be administered or ingested during 4 hours. The other 15 subjects will be assigned to the intervention with cured-ham and after a minimum of 10 h fasting received 65-70 g of Iberian cured-ham. No other food was administered of ingested during 4 hours. At baseline and after 4 hours plasma, blood and urine will be obtained as well as blood pressure and determination of fasting glucose and triglycerides. Anthropometric and lifestyle questionnaire data will be obtained at baseline. RNA will be isolated form blood both at baseline and after 4 hours intervention. RNA will be used for the study of gene expression (focused on genes related to obesity).

The follow-up for all study arms includes the 4 hours between the corresponding first intervention (oranges or Iberian cured-ham), the washout period (1-3 weeks) and the

corresponding second intervention (Iberian cured-ham or oranges) according to the cross over randomised trial.

From plasma an urine stored samples a metabolomic study is proposed to identify markers of the intake of oranges and Iberian cured-ham since the short-term intervention study provides a unique intervention with these foods.

Intervention Type
Other

Primary outcome measure
1. Changes in the expression of genes related to obesity and cardiovascular risk will be measured using RNA isolated from blood at baseline and after intervention (at 4 hours).
1.1. In a subsample, changes in gene expression will be analyzed at the whole transcriptome level by using transcriptome-wide human arrays. The top ranked genes, related to obesity /cardiovascular risk will be selected to analyze their specific gene expression in all the participants by RT-PCR.

Secondary outcome measures
1. Changes in fasting glucose and fasting triglycerides will be measured in fasting plasma by standard procedures from baseline to 4 hours.
2. Changes in blood pressure will be measured from baseline to 4 hours post intervention.
3. Weight, height, waist circumference and body composition by bioimpedance will be measured at baseline.
4. Food intake and adherence to the Mediterranean diet will be measured using the 14-item Mediterranean diet adherence PREDIMED scale at baseline.
5. Physical activity will be measured using the short form of the Minnesota physical activity questionnaire at baseline.
6. Sleep characteristics will be measured using the Pittsburgh Sleep Quality Index questionnaire at baseline.
7. Chronotype will be measured using the Horne and Östberg questionnaire at baseline.
8. Metabolic markers of consumption of oranges and cured ham will be measured using plasma and urine samples at baseline and at 4 hours when additional funding is available.

Overall study start date
23/10/2018

Completion date
20/12/2019

Eligibility

Key inclusion criteria
1. Between 18 and 50 years old

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30 participants

Key exclusion criteria
1. Diseased
2. Allergic or intolerance to oranges or cured-ham
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
27/12/2018

Date of final enrolment
12/07/2019

Locations

Countries of recruitment
Spain

Study participating centre
University of Valencia. School of Medicine
Avda. Blasco Ibanez 15
Valencia
Spain
46010

Study participating centre
CIBER OBN
Instituto de Salud Carlos III. Calle Sinesio Delgado 10

Madrid
Spain
28029

Sponsor information

Organisation
University of Valencia

Sponsor details
Avda. Blasco Ibanez 13
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Sponsor type
University/education

Website
https://www.uv.es/

ROR
https://ror.org/043nxc105

Funder(s)

Funder type
Other

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

Funder Name
Biogenome DX, S.L.

Results and Publications

Publication and dissemination plan
Findings regarding the main hypothesis will be published first in international journals related to nutrition and obesity. Later publications will include further secondary analyses. Posters and oral communications in related scientific meetings are planned.

Intention to publish date
27/12/2020

Individual participant data (IPD) sharing plan
Data will not be available outside the core research group as the informed consent form signed by participants stated that individual level date will not be publicly available. Researchers who are interested in this study can contact the main investigator (Dr JV Sorlí) if they have any questions regarding the data or are interested in further collaborations. The participants will receive written information about what the study involves and sign a consent form before entering the study.

IPD sharing plan summary
Not expected to be made available