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Sofrito bioactive compounds. Metabolomic study and involved mechanisms on control of oxidative stress and inflammation

Submission date
02/06/2016

Recruitment status
No longer recruiting

Registration date
06/07/2016

Overall study status
Completed

Last Edited
18/08/2023

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Antioxidants are substances that may prevent or delay damage to the cells in our bodies by mechanisms such as decrease oxidative stress and inflammation. They are found in many foods, mainly fruit and vegetables. Among them, polyphenols and carotenoids are antioxidants in typical foods like a sofrito. Sofrito is a tomato sauce that contains oil, onion and garlic. The aim of this study is to compare the pharmacokinetics parameters of sofrito bioactive compounds in a group with a previous consumption of a low antioxidant diet for 10 days versus the same group after a high antioxidant diet

Who can participate?
Healthy men between 18 and 32 years of age without a history of cardiovascular disease, any of several chronic diseases or an allergy/intolerance compounds of sofrito, not smoking neither any toxic practice.

What does the study involve?
Each participant is randomly allocated to one of three arms. Those in Arm A eat a diet high in antioxidants for two weeks. Those in Arm B eat a diet low in antioxidants for 2 weeks. Those in Arm 3 (the control arm) eat their normal diet. As it’s a crossover study, all participants are eventually allocated to all three arms, one at a time, but in a random order with a “rest” (or washout) period of two weeks between each arm. Participants eat their usual diet during the washout period. All participants have a medical assessment at the start and end of the study, which includes looking at their clinical history and what they eat, their body measurements, blood pressure and the collection of a 24-hour urine sample. In addition to this, all participants are asked to eat 240 g of a dish called sofrito/ 70kg, and are asked not eat tomato or onion. Additional blood samples and urine samples are then taken from each participant for analyses.

What are the possible benefits and risks of participating?
There are no risks as long as the exclusion criteria are followed.

Where is the study run from?
Department of Nutrition, Food Science and Gastronomy of Food and Nutrition Torribera Campus University of Barcelona (Spain)

When is the study starting and how long is it expected to run for?
January 2016 to December 2016

Who is funding the study?
1. Ministry of Economy and Competitiveness, MINECO
2. Biomedical Research Centre in Physiopathology of Obesity and Nutrition (CIBEROBN)

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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
AGL2013-49083-C3-1-R

Study information

Scientific Title
Clinical effects of sofrito bioactive compounds in healthy and young subjects after a low antioxidants and a high antioxidants diets: A crossover randomized trial

Acronym
SOBIOCOM

Study objectives
Sofrito is a high antioxidants food that would be positive in prevention diseases. People who intake a low antioxidants diet have higher bioavailability of antioxidants compounds than people who intake a high antioxidants diet. This hypothesis is based in the body mechanism to maintain levels of antioxidants into physiological range avoiding overloading of these.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Barcelona. Jordi Alberch Viè, 12/04/2016, ref: IRB00003099

Study design
Open controlled randomized cross over trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet

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

Interventions
Each participant is randomly allocated to one of three arms.

Those in Arm A consume a diet high in antioxidants (a dish called Sofrito) for two weeks. Those in Arm B consume a diet low in antioxidants for 2 weeks. Those in Arm 3 (the control arm) eat their normal diet.

As it’s a crossover study, all participants do all three arms, in a random order with a washout period of two weeks between each arm. Participants consume their usual diet without limitations or specific guidelines during the washout period.

All participants have a medical assessment is at the start and end of the study, which includes clinical history, dietary evaluation, anthropometric (body) measures, clinical blood pressure measurement and the collection of a 24-hour urine sample.

At the end of each intervention period, every participant consumes 240 g of sofrito/ 70kg, but is not allowed to eat tomato or onion. Additional blood samples and urine samples are then taken from each participant for analyses.

Intervention Type
Other

Primary outcome measure
1. Determination and quantification of carotenoids in plasma by HPLC-DAD at 0h, 5h and 24h
2. Bioavailability, identification and quantification of polyphenols in plasma and urine, assessed using LTQ-Orbitrap Mass Spectrometry and HPLC-MS/MS to study the pharmacokinetics parameters at all times between 0 and 24h.

Secondary outcome measures
1. All participants in the study will be clinically examined and subsequently signed an informed consent according to accept their participation in the study
2. At the beginning and end of each intervention period a medical assessment will be performed which includes: clinical history, dietary evaluation, anthropometric measures, clinical blood pressure and 24-hour ambulatory blood pressure and the collection of 24-h urine sample
3. A 1-day and 3-day food record validated nutritional questionnaire will be used at the beginning and end of the intervention to assess nutrient intake and to monitor adherence to the dietary recommendations. We will use the Programa de Càlcul Nutricional Professional (PCN Pro 1.0.32). Physical activity will also be evaluated with the Minnesota Leisure Time Physical Activity questionnaire which has also been validated in Spain

Overall study start date
18/01/2016

Completion date
23/12/2016

Eligibility

Key inclusion criteria
1. Healthy volunteers
2. Males
3. Age 18-32 years

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
32 Years

Sex
Male

Target number of participants
22

Total final enrolment
22

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. Tomato intolerance or allergic or onion or garlic intolerance or allergic
6. Smoking subjects
7. Alcoholism
8. Other toxic abuse

Date of first enrolment
08/02/2016

Date of final enrolment
16/06/2016

Locations

Countries of recruitment
Spain

Study participating centre
Department of Nutrition, Food Science and Gastronomy of Food and Nutrition Torribera Campus (University of Barcelona)
Prat de la Riba, 171
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Sponsor information

Organisation
Gallina Blanca

Sponsor details

Plaza Europa, 41
Barcelona
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Sponsor type
Industry

Website
https://www.gallinablanca.es

Funder(s)

Funder type
Government

Funder Name
Ministerio de Economía y Competitividad

Alternative Name(s)
Ministry of Economy and Competitiveness, MINECO, MEC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Spain

Funder Name
Centro de Investigación Biomédica en Red-Fisiopatología de la Obesidad y Nutrición

Alternative Name(s)
Biomedical Research Center Network on Physiopathology of Obesity and Nutrition, CIBER Physiopathology of Obesity and Nutrition, Centro de Investigacion Biomedica en Red Fisiopatologia de la Obesidad y Nutricion, Centro de Investigación Biomédica en Red de Fisiopatología de la Obesidad y Nutrición, CIBER de Fisiopatología de la Obesidad y Nutrición, CIBEROBN

Funding Body Type
Private sector organisation

Funding Body Subtype
Research institutes and centers

Location
Spain

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date
23/12/2017

Individual participant data (IPD) sharing plan

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	results	14/11/2018	29/01/2019	Yes	No
Results article		15/04/2019	18/08/2023	Yes	No