ISRCTN29145931 https://doi.org/10.1186/ISRCTN29145931

Demonstration of the nutritional benefits of following an organic vs. conventional diets using “omics technologies”

Submission date
26/10/2016

Recruitment status
No longer recruiting

Registration date
16/12/2016

Overall study status
Completed

Last Edited
20/01/2023

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Organic foods are becoming more popular, and are advertised for their benefits to health and the environment. During their production, organic foods are treated more naturally, without the use of additives and chemicals. Some research has found that organic foods contain higher levels of antioxidants, which is thought to be due to the absence of pesticides. More research about the health benefits of organic foods is necessary however. The aim of this study is to investigate the health benefits to the body of eating a healthy, organic diet compared to a healthy, conventional diet.

Who can participate?
Healthy men and women aged between 18 and 40 years..

What does the study involve?
Participants are randomly allocated into one of two groups. For 28 days, those in the first group follow a healthy and organic diet and those in the second group follow a healthy and conventional diet. After this, the two groups swap so they are following the other diet for a further 28 days. At the beginning and end of each diet, participants provide blood, urine, stool and saliva samples. In addition, all participants undergo a medical assessment at the start and end of the study, which includes having their medical history taken, having their diet and physical activity levels recorded, undergoing a range of anthropometric (body) measurements and having their blood pressure tested as well as providing a urine sample.

What are the possible benefits and risks of participating?
There are no direct benefits or risks to participants.

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?
June 2016 to December 2016

Who is funding the study?
1. Government of Catalunya (Spain)
2. Biomedical Research Centre in Physiopathology of Obesity and Nutrition (Spain)

Main contact
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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
53 05012 2016

Study information

Scientific Title
Clinical effects of bioactive compounds from an organic vs. conventional diets (typical Mediterranean diet) in healthy and young subjects: A crossover randomized trial

Acronym
ECOCONDIET

Study objectives
Organic food has more health benefits to the organism than conventional food.

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 randomised 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
Not available in web format, please use the contact details below to request a patient information sheet in Spanish

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

Interventions
Participants are randomised to one of two groups who consume each of the two study diets in a random order. There is a 1.5 month wash-out period between the two dietary interventions during which participants can consume their usual diets.

Intervention A: Participants consume a healthy and organic diet for 28 days
Intervention B: Participants consume a healthy and conventional diet for 28 days

Both interventions follow a very similar dietetic pattern, a healthy diet (typical Mediterranean diet) rich in vegetables foods.

Biological samples (blood, urine, stool and saliva) will be taken at the beginning and end of each intervention (baseline and 28 days). The urine recollection will be for 24 hours before of the test. The blood will be centrifuged and all the samples will be stored at -80ºC until analysis.

Intervention Type
Other

Primary outcome measure

1. Carotenoids in plasma and saliva is measured using HPLC-DAD at the start and end of each of the 28 day intervention periods
2. Bioavailability, identification and quantification polyphenols in stools, plasma, urine and saliva are assessed using LTQ-Orbitrap Mass Spectrometry and HPLC-MS/MS at the start and end of each of the 28 day intervention periods
3. Pesticides in plasma are measured using GC-MS at the start and end of each of the 28 day intervention periods

Secondary outcome measures
1. Adherence to the Mediterranean diet is measured using a questionnaire designed for the purpose of this study at the start and end of each of the 28 day intervention periods
2. Food intake is measured using food frequency questionnaires designed for the purpose of this study at the start and end of each of the 28 day intervention periods
3. Physical activity is evaluated with the Minnesota Leisure Time Physical Activity questionnaire at the start and end of each of the 28 day intervention periods
4. Urine metabolites (metabolomics) are assessed using LTQ-Orbitrap Mass Spectrometry at the start and end of each of the 28 day intervention periods
5. Markers of inflammation are measured by inmunnoassay on plasma samples at the start and end of each of the 28 day intervention periods
6. Constituency of gut microbiota is measured using LTQ-Orbitrap Mass Spectrometry on stool samples at the start and end of each of the 28 day intervention periods

Overall study start date
16/05/2016

Completion date
21/03/2017

Eligibility

Key inclusion criteria
1. Healthy volunteers
2. Males and females
3. Age: 18-40

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
40 Years

Sex
Both

Target number of participants
25

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. Study's foods intolerance or allergic
6. Smoking subjects
7. Alcoholism
8. Other toxic abuse

Date of first enrolment
20/06/2016

Date of final enrolment
23/01/2017

Locations

Countries of recruitment
Spain

Study participating centre
Food and Nutrition Torribera Campus University of Barcelona. Department of Nutrition, Food Science and Gastronomy.
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Sponsor information

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Veritas (Ecoveritas S.A.)

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Sponsor type
Industry

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Organisation
Conservas Monjardín (Conservas José Salcedo Soria S.L.)

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Industry

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Organisation
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Sponsor type
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Funder(s)

Funder type
Government

Funder Name
Government of Catalonia (Generalitat de Catalunya)

Funder Name
Biomedical Research Centre in Physiopathology of Obesity and Nutrition, CIBEROBN

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
28/02/2018

Individual participant data (IPD) sharing plan
Not provided at time of registration

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		24/08/2019	20/01/2023	Yes	No