

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

<b>Submission date</b> 26/10/2016	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results <input type="checkbox"/> Individual participant data
<b>Registration date</b> 16/12/2016	<b>Overall study status</b> Completed	
<b>Last Edited</b> 20/01/2023	<b>Condition category</b> Nutritional, Metabolic, Endocrine	

## 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

Dr Rosa M. Lamuela-Raventós

## Contact information

**Type(s)**

Public

**Contact name**

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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 -80°C 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 immunoassay 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.**

Prat de la Riba, 171

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**Sponsor information****Organisation**

Veritas (Ecoveritas S.A.)

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**Sponsor type**

Industry

**Website**

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

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Industry

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Can Feixes

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Industry

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[www.codorniuraventos.com/es/bodegas/raimat](http://www.codorniuraventos.com/es/bodegas/raimat)

**Organisation**

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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?
<a href="#">Results article</a>		24/08/2019	20/01/2023	Yes	No