

Investigating whether a person's genes or sex affects the range of microbes in their gut when they eat a Mediterranean or Western diet

Submission date 25/12/2019	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 02/01/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 03/01/2023	Condition category Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

The gut microbiome is the ecosystem of bacteria, fungi and other microorganisms that live in a person's gut. It is complex and highly individual. The variety of microbes present depends on some factors that cannot be changed, such as a person's genetic make-up, sex and age, as well as factors such as diet, illness and drug treatment. It is not currently known how to change the composition of the microbiome through diet.

This trial aims to investigate the gut microbiome in people who eat a Mediterranean diet and those who eat a Western, non-Mediterranean diet to explore whether there are any patterns or any genes that are associated with a healthy gut microbiome.

Who can participate?

Men and women aged 18-75 years who eat either a Mediterranean diet or a Western, non-Mediterranean diet

What does the study involve?

The participants will provide a stool sample and a blood sample before the start of the study. They will have some physical measurements taken (height, weight, waist circumference) and will also fill in questionnaires asking about their diet, physical activity, sleep etc. They will be asked to continue to eat a Mediterranean diet or a Western, non-Mediterranean diet for 8 months and will then provide the samples and measurements and fill out the questionnaires again.

What are the possible benefits and risks of participating?

In this study, no risks or benefits to participants are expected.

Where is the study run from?

University of Valencia (Spain) and FISABIO (Spain)

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

January 2019 to February 2022

Who is funding the study?
FISABIO (Spain) , University of Valencia (Spain), CIBEROBN (Spain) and CIBERESP (Spain)

Who is the main contact?
Professor Dolores Corella, dolores.corella@uv.es

Contact information

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Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

PCT4E-19

Study information

Scientific Title

Microbiome-Genome interaction in two dietary contexts with a gender perspective

Acronym

MicroGenDiet

Study objectives

The intestinal microbiome is a complex and dynamic ecosystem that has co-evolved with humans. However, its composition presents a great interindividual variability, being influenced by a series of intrinsic factors such as the age, sex and genotype of the individual and extrinsic factors such as diet, antibiotics or health status. Diet is the environmental factor that has the greatest effect on the composition of the intestinal microbiota. However, the interindividual variability makes it difficult to use diet as a modulating tool to correct the alteration of the microbiota associated with different pathologies since, in many cases, the response is specific to each individual. In our proposal we will address the problem of inter-individual variability of the microbiome by evaluating the effect of genetic determinants and sex on the composition and function of the microbiota in the framework of two types of diets, Mediterranean diet and Western diet.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 05/12/2019, Ethics Committee of Human Research at the University of Valencia (Avenida Blasco Ibáñez, 13, Valencia 46010, Spain; +34 963864109; vicerec.investigacio@uv.es), ref: UV-INV_ETICA1206333

Study design

A longitudinal study will be carried out. Samples and data will be obtained at baseline and after 8-months of follow-up. Two groups of diets will be compared in an observational design. Mendelian randomization will be used for some analyses.

Primary study design

Observational

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Gut microbiome in people following two dietary patterns

Interventions

A longitudinal study will be carried out. Samples and data will be obtained at baseline and after 8 months of follow-up. Two groups of diets will be compared in an observational design.

Mendelian randomization will be used for some analyses.

Two dietary patterns (high adherence to the Mediterranean diet group and low adherence to the Mediterranean diet group/Western dietary pattern) will be investigated.

A screening of compliance criteria for volunteers will be carried out. A validated Mediterranean diet adherence questionnaire will be administered and according to the score, the person will be included or not in the dietary groups. After this classification at baseline, subjects will receive advice to maintain their usual dietary pattern for 8 months of follow-up.

Intervention Type

Behavioural

Primary outcome(s)

Current primary outcome measures as of 03/01/2023:

1. Composition of bacteria and fungi in stool samples assessed using DNA sequencing at baseline and 6 months
2. Metabolic functions of the microbiota assessed using bioinformatic tools at baseline and 6 months
3. Host genomic profile assessed using a genome-wide genotyping array at baseline

Previous primary outcome measures:

1. Composition of bacteria and fungi in stool samples assessed using DNA sequencing at baseline and 8 months
2. Metabolic functions of the microbiota assessed using bioinformatic tools at baseline and 8 months
3. Host genomic profile assessed using a genome-wide genotyping array at baseline

Key secondary outcome(s)

Current primary outcome measures as of 03/01/2023:

1. Host genome-wide determinations assessed by microarray at baseline
2. Blood pressure measured using standard methods at baseline and longitudinally at 6 months
3. Weight measured using validated scales and bioimpedance at baseline and 6 months
4. Height measured using standard methods at baseline and 6 months
5. Waist circumference measured using standard methods at baseline and 6 months
6. Body composition measured by bioimpedance at baseline and 6 months
7. Food intake and adherence to the Mediterranean diet will be measured using the 14-item Mediterranean diet adherence PREDIMED score at baseline and 6 months
8. Dietary intake assessed using dietary questionnaires (24-h recalls and food frequency questionnaires) at baseline and 6 months
9. Physical activity measured using the short form of the Minnesota physical activity questionnaire at baseline and 6 months
10. Sleep characteristics measured using the Pittsburgh Sleep Quality Index questionnaire at baseline and after 6 months
11. Chronotype (i.e. morning or evening person) measured using the Horne and Östberg questionnaire at baseline
12. Cognitive function measured using the TMT-A, TMT-B, COWAT and Wechsler Adult Intelligence Scale-III tests at baseline and after 6 months

13. Plasma lipids measured using standard methods at baseline and after 6 months
 14. Fasting glucose measured using colorimetric methods at baseline and after 6 months
 15. Bilirubin measured using colorimetric methods at baseline and after 6 months
 16. Blood counts measured using standard methods at baseline and after 6 months
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13. Plasma lipids measured using standard methods at baseline and after 8 months
14. Fasting glucose measured using colorimetric methods at baseline and after 8 months
15. Bilirubin measured using colorimetric methods at baseline and after 8 months
16. Blood counts measured using standard methods at baseline and after 8 months

Completion date

15/02/2022

Eligibility

Key inclusion criteria

1. Aged 18-75 years with 50% females
2. Has a dietary profile (Mediterranean diet or Western diet)

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

75 years

Sex

All

Total final enrolment

102

Key exclusion criteria

1. Received antibiotics or prebiotics or probiotics in the last 6 months
2. Diseased
3. Immunodeficient or HIV-positive
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 addiction
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. Pregnant or breastfeeding women
14. Any other condition that may interfere with the completion of the study protocol

Date of first enrolment

30/12/2019

Date of final enrolment

01/07/2021

Locations**Countries of recruitment**

Spain

Study participating centre**University of Valencia**

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Sponsor information

Organisation

Fisabio

Organisation

University of Valencia

Organisation

CIBEROBN

Organisation

Centro de Investigación Biomédica en Red de Epidemiología y Salud Pública

Funder(s)

Funder type

Research organisation

Funder Name

Fundación para el Fomento de la Investigación Sanitaria y Biomédica de la Comunitat Valenciana (FISABIO)

Funder Name

University of Valencia

Funder Name

CIBEROBN

Funder Name

Centro de Investigación Biomédica en Red de Epidemiología y Salud Pública (CIBERESP)

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to restrictions in the informed consent. Participants did not consent to share data.

IPD sharing plan summary

Not expected to be made available