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Does a 24-h fasting period change gene expression and methylation in comparison with a frequent meal pattern?

Submission date 11/12/2019	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 13/12/2019	**Overall study status** Completed	
Last Edited 14/07/2022	**Condition category** Other	

Plain English summary of protocol

Background and study aims
Diet is one of the main factors related to gene expression and methylation. There are some genes for which a high level of expression or methylation is protective against ageing or cardiometabolic disease. For other genes increased gene expression is detrimental. Energy restriction or even fasting has been related to protection against ageing and some metabolic diseases. This protection may be mediated by a better autophagy function in animal models. However, the results in humans are scarce. Therefore, the aim of this study is to analyze the influence of a 24-hour fast compared to a pattern of frequent meals in the expression and methylation of selected genes related to autophagy and biological age in adults from a healthy general population.

Who can participate?
Healthy men and women from the general population (aged 25-50 years)

What does the study involve?
Two interventions are compared in a crossover design (each participant receives both interventions in a random order): a) fasting for 24 hours and b) a pattern of frequent meals (consisting of eating 6 times a day with a 3-hour period between each intake). The intake consists of a Mediterranean diet pattern composed of complex carbohydrates, mainly brown rice, vegetables, white meat in the form of chicken, and fruit. The intervention and follow-up are 2 days each, with a "wash-out" period of 2 weeks between interventions.

What are the possible benefits and risks of participating?
Participants will be informed that there are no benefits and risks expected.

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

When is the study starting and how long is it expected to run for?
October 2019 to December 2023

Who is funding the study?
University of Valencia (Spain)

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

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
PCT1E-19

Study information

Scientific Title
Effect of 24-hour fasting versus frequent meals on selected gene expression and methylation: a cross-over randomized and controlled trial

Acronym
FASTING-24

Study objectives

The hypothesis is that short-term fasting, in comparison with a frequent meal pattern, can modify the expression level and/or the methylation of some genes, mainly, those related to autophagy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 05/12/2019, Institutional review board of Valencia University (human subjects) (Avda. Blasco Ibanez 13, Valencia, 46010, Spain; +34 (0)963864109; vicerec.investigacio@uv.es), ref: UV-INV_ETICA-1205601

Study design
Interventional randomised cross over trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Effect of fasting and a regular meal pattern on gene expression

Interventions
This is a short term cross-over randomized trial including 10 participants. Participants will be randomly assigned 1:1 to the order of the two interventions by simple random assignment through a computer program:
1. Fasting for 24 hours
2. Pattern of frequent meals (consisting of eating 6 times a day having a 3 hour period between each intake). The intake will consist of a Mediterranean Diet pattern composed of complex carbohydrates, mainly brown rice, vegetables, white meat in the form of chicken, and fruit.

The intervention and follow-up will be 2 days for each treatment in a crossover design. A "wash-out" period of 2 weeks between treatments will be undertaken.

Intervention Type
Other

Primary outcome(s)
Methylation and expression of genes related to autophagy measured using DNA and RNA isolated from blood at baseline and after each intervention (at 4 hours)

Key secondary outcome(s))
1. Fasting glucose and fasting triglycerides measured in fasting plasma by standard procedures from baseline to 4 hours
2. Blood pressure measured from baseline to 4 hours post intervention
3. Weight, height, waist circumference and body composition by bioimpedance measured at baseline
4. Food intake and adherence to the Mediterranean diet measured using the 14-item

Mediterranean diet adherence PREDIMED scale at baseline
5. Physical activity measured using the short form of the Minnesota physical activity questionnaire at baseline
6. Sleep characteristics measured using the Pittsburgh Sleep Quality Index questionnaire at baseline
7. Chronotype measured using the Horne and Östberg questionnaire at baseline

Completion date
17/12/2023

Eligibility

Key inclusion criteria
1. Volunteers recruited from the general population
2. Between 25 and 50 years old
2. BMI between 23 and 33 kg/m2

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
25 years

Upper age limit
50 years

Sex
All

Key exclusion criteria
1. Diseased
2. Diabetics
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 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. Any other condition that may interfere with the completion of the study protocol

Date of first enrolment
20/12/2019

Date of final enrolment
15/06/2023

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

Funder(s)

Funder type
University/education

Funder Name
Universitat de València

Alternative Name(s)
University of Valencia, UV

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Spain

Results and Publications

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 data 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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes