ISRCTN17200423 https://doi.org/10.1186/ISRCTN17200423

Discovery of novel biomarkers of legumes intake

Submission date	Recruitment status	[_] Prospectively registered
08/02/2017	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
28/02/2017	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
04/06/2024	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol

Background and study aims
Legumes (e.g., (lentils, chickpeas, white beans) are nutrient-rich foods that as part of healthy diet have been found to improve glycaemic (blood sugar) control and weight management, as well as to reduce blood pressure and cholesterol levels. Therefore, there is a growing interest to assess the association between eating legumes and the risk of develop chronic (long-term) diseases. An accurate assessment of legumes consumption by testing the levels of substances called biomarkers in biological fluids (e.g., blood, urine) is key to understanding these relationships. The aim of this study is to find new biomarkers of legumes intake.

Who can participate?
Healthy non-smoking adults, between 18 and 40 years of age, not taking any regular medication or supplements, without any chronic or infectious disease, and free of allergy, intolerance or aversion to legumes.

What does the study involve?
Each participant is randomly allocated to eat one of four different foods (lentils, chickpeas, white beans or pasta). Blood and urine samples are taken, and then a large portion of one of the foods is given to each participant. Blood samples are taken up to 6 hours after eating each food, as well as 24 and 48 hours later. Urine samples are also collected at different intervals during the 48 hours after eating each food. After this, participants attend three further study visits, repeating the procedure with the other three foods.

What are the possible benefits and risks of participating?
There are no direct benefits to participants, other than having a health check as part of the screening. There are no notable risks of taking part. However, there is a small risk of bruising when giving a blood sample, but this is reduced by the use of experienced nursing staff.

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

When is the study starting and how long is it expected to run for?
January 2016 to December 2018

Who is funding the study?
1. Joint Programming Initiative (JPI-HDHL, EU)
2. Ministry of Economy and Competitiveness (MINECO, Spain)
3. University of Barcelona (UB, Spain)

Who is the main contact?
Dr Cristina Andres-Lacueva

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Discovery of novel biomarkers of legumes intake using a metabolomics based approach

Study objectives
Following an intake of legumes, metabolites related to their nutritional composition will increase in urine and blood. The potential of these metabolites as candidate biomarkers of legumes intake will be evaluated.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Bioethical Committee of the University of Barcelona, 17/11/2015, ref: IRB00003099.

Study design
Randomized cross-over trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Other

Study type(s)
Other

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

Health condition(s) or problem(s) studied
Biomarkers of food intake

Interventions
Volunteers will consume one of the following foods in a random order: lentils, chickpeas, white beans and pasta. These foods will be consumed on separate study visits, and baseline and postpandrial blood samples will be taken up to 6 hours following consumption, as well as a fasting blood sample 24 and 48 hours after the intake of each food. Urine samples will be also collected at baseline and at different intervals during the 48 hours post-consumption of each food.

Intervention Type
Other

Primary outcome measure
Presence of biomarkers of legumes consumption in blood and urine, measured using an untargeted metabolomics approach. Fasting blood and urine samples are collected before the intake of each food. Then, postpandrial blood samples are taken after 1, 2, 4 and 6h; and additional fasting blood samples 24 and 48 hours after the intake of each food. In parallel, urine samples are also collected in the following intervals post-consumption of each food: 0-1h, 1-2h, 2-4h, 4-6h, 6-12h, 12-24h, 24-48h.

Secondary outcome measures
No secondary outcome measures

Overall study start date

10/01/2016

Completion date
31/12/2018

Eligibility

Key inclusion criteria
1. Healthy adults aged between 18 and 40 years old
2. Non-smokers
3. BMI >18.5 or < 30 kg/m2
4. Weight >55 kg
5. Free of chronic or infectious disease
6. Not pregnant, planning a pregnancy or lactating
7. Not taking any regular medication (oral contraceptive pill is allowed)
8. Not taking supplements
9. No antibiotics in the 6 previous months
10. No allergy or aversion to legumes or pasta
11. Not anaemic
12. No blood donation within the last 2 months

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
12

Total final enrolment
11

Key exclusion criteria
1. Smokers
2. Diagnosed anaemia or another health condition (chronic or infectious disease)
3. Blood donation during the previous 2 months
4. Allergy, intolerance or aversion to legumes or pasta
5. Taking medication or supplements (oral contraceptive pill is allowed)
6. Pregnant, planning a pregnancy or lactating

Date of first enrolment
10/01/2016

Date of final enrolment
30/06/2016

Locations

Countries of recruitment
Spain

Study participating centre
Department of Nutrition, Food Science and Gastronomy
Faculty of Pharmacy and Food Science
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Sponsor information

Organisation
University of Barcelona

Sponsor details
Biomarkers and Nutritional & Food Metabolomics Research Group
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Sponsor type
University/education

Website
http://nutrimetabolomics.com/

ROR
https://ror.org/052g8jq94

Funder(s)

Funder type
Government

Funder Name
Joint Programming Initiative - Healthy Diet for Healthy Lifestyle (JPI-HDHL)

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

Results and Publications

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

Intention to publish date
31/12/2018

Individual participant data (IPD) sharing plan
The current data sharing plans for the study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	11/07/2018	14/06/2019	Yes	No
Other publications	Impact of sample treatment	02/06/2023	04/06/2024	Yes	No