

Dietary biomarkers of commonly consumed foods

Submission date 07/01/2016	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 15/01/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 10/10/2022	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Assessment of dietary intake is key to understand the links between diet and health. Here, researchers are going to study molecules in urine and blood samples to that them an insight into what people have eaten. These new molecules are called dietary biomarkers. This study will help to identify new molecules that can act as biomarkers of commonly consumed foods. These can then be used in the assessment of diet, identification of diet-related diseases and used how to explain how a dietary intervention (programme) will work , thereby adding to scientific knowledge.

Who can participate?

Healthy adults between 18-60 with a body mass index (BMI) between 18.5 and 30 kg/m2.

What does the study involve?

Each participant is asked to eat one of each of the following foods at a time, in a random order: broccoli, red bell peppers, oranges, apples, madeira sponge cake, spaghetti, white bread, wholemeal bread and cheddar cheese. They are asked for urine and blood samples for up to 4 hours after eating each food. They are also asked for a fasting blood sample and urine sample one day after eating the foods. The samples are then analysed for dietary biomarkers.

What are the possible benefits and risks of participating?

There are no known benefits or risks to taking part in this study.

Where is the study run from?

University College Dublin (Ireland)

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

December 2015 to December 2017

Who is funding the study?

European Research Council (Belgium)

Who is the main contact?
Professor Lorraine Brennan

Contact information

Type(s)
Scientific

Contact name
Prof Lorraine Brennan

ORCID ID
<http://orcid.org/0000-0002-7711-7499>

Contact details
University College Dublin (UCD)
UCD Institute of Food and Health
Dublin
Ireland
D4

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The identification of dietary biomarkers using a metabolomics based approach

Study objectives
Small molecules found in biofluids will reflect dietary intake of specific foods.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University College Dublin (UCD) Human Research Ethics Committee – Sciences, 08/12/2015, ref: LS-15-69-Brennan

Study design

Single centre randomised 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 contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Dietary biomarkers

Interventions

Randomised study where subjects will consume one of the following in random order on one occasion only and samples will be collected following consumption (up to 4 h post consumption): Broccoli, red bell peppers, oranges, apples, madeira sponge cake, spaghetti, white bread, wholemeal bread and cheddar cheese.

One day after consumption of the foods a fasting blood and urine sample will also be collected.

Intervention Type

Other

Primary outcome measure

Identification of markers in blood and urine that relate to the consumption of the food.

Secondary outcome measures

No secondary outcome measures

Overall study start date

01/12/2015

Completion date

01/12/2017

Eligibility

Key inclusion criteria

1. Healthy adults aged between 18 and 60 years old
2. BMI > 18.5 and < 30 kg/m²

Participant type(s)

Healthy volunteer

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

24 including a 20% dropout

Key exclusion criteria

1. Smokers
2. Diagnosed health condition (chronic or infectious disease)
3. Taking medication (oral contraceptive pill is allowed)
4. Pregnant, lactating
5. Allergies/intolerances to any of specified test foods

Date of first enrolment

04/01/2016

Date of final enrolment

01/01/2017

Locations

Countries of recruitment

Ireland

Study participating centre

University College Dublin (UCD)

Dublin 4

Dublin

Ireland

D4

Sponsor information

Organisation

University College Dublin

Sponsor details

Belfield
Dublin
Ireland
D4

Sponsor type

University/education

ROR

<https://ror.org/05m7pjf47>

Funder(s)

Funder type

Government

Funder Name

European Research Council

Alternative Name(s)

ERC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Results and Publications

Publication and dissemination plan**Intention to publish date**

01/12/2017

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?
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Results article	Biomarkers of apple intake	20/04/2020	10/10/2022	Yes	No
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