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Dietary biomarkers of commonly consumed foods

Submission date	Recruitment status	[_] Prospectively registered
07/01/2016	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
15/01/2016	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
10/10/2022	Nutritional, Metabolic, Endocrine	

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

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Contact details
University College Dublin (UCD)
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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?

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