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Discovery of novel biomarkers of food intake

Submission date	Recruitment status	[X] Prospectively registered
21/12/2015	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
23/12/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
28/06/2019	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol

Background and study aims
Studies looking at the relationship between diet and health require ways of accurately measuring what a person consumes (dietary exposure). It can be very difficult to accurately assess food intake however, as classic methods such as food diaries and food frequency questionnaires are often misleading. It has been suggested that it may be possible to test the body to look for evidence that a particular food has been consumed. By testing bodily fluids such as blood or urine, levels of biomarkers (chemical indicators in the body, such as a specific protein), it may be possible to find a way of accurately measuring whether a person has consumed a particular food. This study aims to identify new biomarkers of food intake with a specific focus on vegetables.

Who can participate?
Healthy, Caucasian adults who are not taking any supplements

What does the study involve?
Participants are randomly allocated to one of four groups, who eat four different foods (carrots, peas, turnips and couscous) at four different study visits, in a random order. At each study visit, participants have a sample of blood and urine taken and are then given a large portion of one of the foods to eat. After six hours, further blood and urine samples are taken, in order to test whether there are any biomarkers that were not present before the food was eaten. Participants are then asked to avoid that specific food for 48 hours, and have repeat blood and urine samples taken at 24 and 48 hours. Following 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 taking part in the study. There are no notable risks of taking part, however participants may experience some pain, discomfort and bruising from the blood tests.

Where is the study run from?
University College Dublin (UK)

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 (Ireland)
2. Science Foundation Ireland (Ireland)
3. University College Dublin (Ireland)

Who is the main contact?
Professor Lorraine Brennan

Contact information

Type(s)
Scientific

Contact name
Prof Lorraine Brennan

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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 carrots and legumes intake

Study objectives
Following food intake biomarkers specific to the food will appear in urine and blood.

Ethics approval required
Old ethics approval format

Ethics approval(s)

University College Dublin Human Research Ethics Committee – Sciences, 05/11/2015, ref: LS-15-63-Brennan

Study design
Randomised cross-over study

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 below to request a patient information sheet.

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

Interventions
Participants are randomly allocated to one of four groups, who will each consume one of the following foods in random order.

Food A: Carrots
Food B: Peas
Food C: Turnips
Food D: Couscous

Large portions of each food will be consumed on separate study visits (4 study day visits) and postprandial samples will be taken up to 6 hours following consumption. A fasting sample will also be taken 24 and 48 hours post consumption of each food. The foods of interest will be avoided by participants during this time period.

Intervention Type
Other

Primary outcome measure
Presence of biomarkers of food intake in urine and blood are measured 6 hours post-consumption of each food and at 24 and 48 hours post-consumption.

Secondary outcome measures
N/A

Overall study start date
04/01/2016

Completion date
01/12/2018

Eligibility

Key inclusion criteria
1. Caucasian adults
2. Non smokers
3. BMI >18.5 and <30 kg/m2
4. Free of chronic or infectious disease
5. Not taking any medication (oral contraceptive pill is allowed)
6. Not taking supplements
7. Not pregnant, lactating
8. No antibiotics in the 6 previous months

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
12

Total final enrolment
16

Key exclusion criteria
BMI greater than 30 kg/m2

Date of first enrolment
04/01/2016

Date of final enrolment
01/12/2016

Locations

Countries of recruitment
Ireland

Study participating centre
University College Dublin
Institute of Food and Health
Belfield
Dublin
Ireland
Dublin 4

Sponsor information

Organisation
University College Dublin

Sponsor details
Belfield
Dublin
Ireland
D4

Sponsor type
University/education

Website
http://www.ucd.ie/foodandhealth/

ROR
https://ror.org/05m7pjf47

Funder(s)

Funder type
Not defined

Funder Name
Joint Programming Initiative

Funder Name
Science Foundation Ireland

Alternative Name(s)
SFI

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Ireland

Funder Name
University College Dublin

Alternative Name(s)
UCD

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Ireland

Results and Publications

Publication and dissemination plan
Planned publication of study results in a peer reviewed journal.

Intention to publish date
31/12/2018

Individual participant data (IPD) sharing plan

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	pea intake biomarker results	04/12/2018	28/06/2019	Yes	No