Discovery of novel biomarkers of food intake

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered	
21/12/2015		☐ 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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Contact details

University College Dublin Belfield Dublin Ireland Dublin 4

Additional identifiers

Protocol serial number

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

Study type(s)

Other

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(s)

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.

Key secondary outcome(s))

N/A

Completion date

01/12/2018

Eligibility

Kev 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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

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

Individual participant data (IPD) sharing plan

IPD sharing plan summaryNot expected to be made available

Study outputs

Output type			Date added Peer reviewed?	Patient-facing?
Results article	pea intake biomarker results	04/12/2018	28/06/2019 Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025 No	Yes