ISRCTN88921234 https://doi.org/10.1186/ISRCTN88921234

Identification of metabolomic biomarkers to assess dietary exposure in free-living adults

Submission date	Recruitment status
03/04/2014	No longer recruiting
Registration date	**Overall study status**
03/04/2014	Completed
Last Edited	**Condition category**
18/11/2021	Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
The aim of this study is to find a new way of measuring what people eat and drink on a regular basis. What people eat and drink and how it is prepared can affect our weight and our chances of developing certain diseases, such as heart disease, diabetes and many cancers. The aim is to understand what substances end up in the urine and blood after eating different foods and drinks, and whether these chemicals can be used to identify what someone has been eating, how much, how long ago, how it was cooked and the quality. The study's findings should enable better monitoring of the nation's diet and whether people are following healthy eating guidelines.

Who can participate?
Healthy people between the ages of 18-80 who are normal weight or overweight and live in the North East of England

What does the study involve?
Over a two or three week period, participants follow set meal plans and collect urine samples at regular times. The meal plans are made up of regular food and organised into a normal meal pattern. Participants visit the research facility at the beginning of each week to collect their food and drink. They make a second visit to the research facility at the end of each week to give a blood sample, return the urine samples they collected, and discuss how the study went for them.

What are the possible benefits and risks of participating?
There are no direct benefits to those taking part, but participating may help the researchers to develop a more accurate way of measuring what food and drink people consume on a regular basis and how healthy the British diet is. Participants may experience minor discomfort when giving blood and mild bleeding or bruising afterwards. If a participant has never eaten some of the test foods, there is a very small chance of an allergic reaction. However, all the foods are commonly eaten by most people and participants are asked to declare any known food allergy before joining the study.

Where is the study run from?
The study is a collaboration between Newcastle University, Aberystwyth University and Imperial

College London, but all participants come to the Newcastle University research facilities to take part.

When is the study starting and how long is it expected to run for?
March 2014 to December 2014

Who is funding the study?
Medical Research Council (UK)

Who is the main contact?
1. Dr Naomi Willis (naomi.willis@ncl.ac.uk)
2. Prof. John Mathers (john.mathers@ncl.ac.uk)

Contact information

Type(s)
Scientific

Contact name
Dr Naomi Willis

Contact details
Human Nutrition Research Centre
Institute of Cellular Medicine
Newcastle University
Campus for Ageing and Vitality
Newcastle Upon Tyne
United Kingdom
NE4 5PL
-
naomi.willis@ncl.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
16037

Study information

Scientific Title
Identification of metabolomic biomarkers to assess dietary exposure in free-living adults

Acronym
MAIN

Study objectives
Current strategies for reducing chronic disease burden in the UK emphasize the importance of changing dietary habits. Determining the effectiveness of healthy eating initiatives requires robust tools to assess dietary intake at the population level. The aim of this study is to identify novel chemicals (biomarkers) in blood and urine which are associated with healthy and unhealthy diets.

Ethics approval required
Old ethics approval format

Ethics approval(s)
First MREC approval date 14/01/2014, ref: 14/EM/0040

Study design
Randomised; Interventional; Design type: Not specified

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Diagnostic

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
Topic: Metabolic and endocrine disorders; Subtopic: Metabolic and Endocrine (all Subtopics); Disease: Metabolic & Endocrine (not diabetes)

Interventions
Participants will be given short-term diets lasting three days and will take part for a maximum of three consecutive weeks. These diets will contain specific test foods deemed to have high public health importance (oily fish, wholegrain foods, fruits and vegetables), as well as high fat and sugary foods which are associated with obesity. Participants will follow the diets in different orders and the order they follow will be decided by a random number generator (random.org). Whilst provided with these diets, urine and blood samples will be collected to identify new biomarkers for these different foods/food groups and to establish the optimum urine sampling procedure which has minimal intrusion on normal daily life but is suitable for assessment of dietary exposure in large scale epidemiological studies. No follow-up will take place after the study has been completed.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Clearly distinguishable metabolomic profiles for chosen foods/food groups, measured using mass spectrometry from samples collected on Days 1 - 5 of each study week

Secondary outcome measures
1. Distinguishable metabolomic profiles for chosen foods when using minimally invasive urine sampling
2. Distinguishable metabolomic profiles for different food formulations
Both measured using mass spectrometry from samples collected on Days 1 - 5 of each study week

Overall study start date
31/03/2014

Completion date
19/12/2014

Eligibility

Key inclusion criteria
1. Age 18-80
2. Male or female
3. Normal weight or overweight (body mass index 18.5-29.9 kg/m2)

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
80 Years

Sex
Both

Target number of participants
Planned Sample Size: 30; UK Sample Size: 30

Total final enrolment
51

Key exclusion criteria

1. Weight change of more than 3kg in the preceding 2 months
2. Current smokers
3. Substance abuse
4. Excess alcohol intake
5. Pregnancy
6. Diabetes (Type 1 and Type 2)
7. Cardiovascular disease
8. Cancer
9. Gastrointestinal disease e.g. inflammatory bowel disease or irritable bowel syndrome
10. Kidney disease
11. Liver disease
12. Pancreatitis
13. Food allergy
14. Use of medications likely to interfere with energy metabolism, appetite regulation and hormonal imbalance, including but not exclusive to: antiinflammatory drugs (NSAIDs), steroids or other immunosuppressive medication, androgens, phenytoin, erythromycin or thyroid hormones

Subjects with the above conditions/taking the above medications would have an altered pattern of hormones and inflammatory molecules because of their disease process which may lead to misleading results.

Date of first enrolment
31/03/2014

Date of final enrolment
19/12/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Human Nutrition Research Centre
Institute of Cellular Medicine
Newcastle University
Campus for Ageing and Vitality
Newcastle Upon Tyne
United Kingdom
NE4 5PL

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

Sponsor details
Claremont Wing
Royal Victoria Infirmary
Queen Victoria Road
Newcastle Upon Tyne
England
United Kingdom
NE1 4LP

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (UK); Grant Codes: MR/J010308/1

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication of methodology and findings in relevant peer reviewed journals by December 2017.

Intention to publish date

01/12/2017

Individual participant data (IPD) sharing plan

The current data sharing plans for the current 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		21/10/2020	18/11/2021	Yes	No
HRA research summary			28/06/2023	No	No