

Dietary biomarker discovery using metabolomics

Submission date 25/10/2013	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 25/10/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 29/09/2022	Condition category Other	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
14813

Study information

Scientific Title

Dietary biomarker discovery using metabolomics

Study objectives

Current strategies for reducing chronic disease burden in the UK and elsewhere emphasize the importance of changing dietary habits. Developing population level dietary interventions and monitoring their effectiveness require robust tools for assessing dietary exposure in large scale studies. The aim of the present study is to identify novel chemicals in blood and urine that are associated with a healthy diet. Volunteers will be given diets differing in amounts of specific test foods deemed to have high public health importance (oily fish, wholegrain foods, fruits and vegetables). Whilst provided with these diets urine and blood samples will be collected to determine new biomarkers for these different food sources.

Ethics approval required

Old ethics approval format

Ethics approval(s)

13/LO/0078; First MREC approval date 28/01/2013

Study design

Randomised interventional treatment trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Treatment

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: Primary Care Research Network for England; Subtopic: Not Assigned; Disease: All Diseases

Interventions

Excellent diet, 100% healthy eating target

Good diet, 75% health eating target

Medium diet, 50% healthy eating target

Poor diet, 25% of health eating target

Follow Up Length: 1 month

Study Entry: Single Randomisation only

A formal power calculation is not possible as this will be the first study of its type. However, recent studies have demonstrated significant changes in metabolomics profiles in cohorts of 20 volunteers. Allowing for a dropout rate of 33% we intend to recruit 30 volunteers for the research.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

New dietary biomarker; timepoint(s): 4 weeks

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/09/2013

Completion date

05/01/2015

Eligibility**Key inclusion criteria**

1. Aged between 21 and 65 years
2. Male or female with a body mass index (weight in kg over height in metres squared) between 20-35

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

UK Sample Size: 30

Total final enrolment

19

Key exclusion criteria

1. Weight change of more than 3 kg in the preceding 2 months
2. Current smokers
3. Substance abuse

4. Excess alcohol intake
5. Pregnancy
6. Diabetes
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. Use of medications including: antiinflammatory drugs or steroids, androgens, phenytoin, erythromycin or thyroid hormones

Date of first enrolment

01/09/2013

Date of final enrolment

05/01/2015

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Du Cane Road

London

United Kingdom

W12 0NN

Sponsor information

Organisation

Imperial College Healthcare NHS Trust (UK)

Sponsor details

International Centre for Circulatory Health

59 North Wharf Road

London

England

United Kingdom

W2 1LA

Sponsor type

Hospital/treatment centre

Website

<http://www.imperial.nhs.uk/>

ROR

<https://ror.org/056ffv270>

Funder(s)

Funder type

Research council

Funder Name

MRC CTU (UK); Grant Codes: MR/J010308/1

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan**

Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2017		Yes	No
Results article		22/09/2022	29/09/2022	Yes	No
HRA research summary			28/06/2023	No	No