

Dietary biomarker discovery using metabolomics

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

New dietary biomarker; timepoint(s): 4 weeks

Key secondary outcome(s))

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

Study participating centre

Du Cane Road

London

United Kingdom

W12 0NN

Sponsor information

Organisation

Imperial College Healthcare NHS Trust (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

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
results

Date created Date added Peer reviewed? Patient-facing?

<u>Results article</u>	01/03/2017	Yes	No
<u>Results article</u>	22/09/2022	29/09/2022 Yes	No
<u>HRA research summary</u>		28/06/2023 No	No
<u>Participant information sheet</u>	Participant information sheet	11/11/2025	11/11/2025 No