ISRCTN92541398 https://doi.org/10.1186/ISRCTN92541398

Evaluation of a urinary test to assess vitamin B12 status in older people

Submission date	Recruitment status
07/05/2010	No longer recruiting
Registration date	**Overall study status**
14/07/2010	Completed
Last Edited	**Condition category**
15/03/2013	Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N05077

Study information

Scientific Title
Urinary MMA revisited: a functional biomarker of B12 status applicable to large scale surveys. Part 2: The Intervention Study

Acronym
UMMA 2

Study objectives
Urinary methylmalonic acid (MMA) is a robust, sensitive functional biomarker of vitamin B12 status that can be used in large scale surveys.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Sheffield Research Ethics Committee (NHS) approved on the 7th of April 2008 (ref: 08 /H1309/4)

Study design
Interventional 4 arm double blind randomised placebo controlled parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Screening

Participant information sheet
Not available in web format, please use contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
public health/nutrition particularly in older people; B12 deficiency

Interventions
Capsules containing 0µg, 10µg, 100µg and 500µg Vitamin B12. One daily for 8 weeks.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Urinary MMA, assessed at baseline (week 0), 2, 4, 6 and 8 weeks
2, Plasma B12, assessed at baseline and 8 weeks

Secondary outcome measures
1. Serum holotranscobalamin
2. Plasma total folate
3. Plasma homocysteine
4. Plasma pepsinogen
5. Plasma MMA
All secondary outcomes will be assessed at baseline and 8 weeks.

Overall study start date
01/01/2010

Completion date
30/12/2010

Eligibility

Key inclusion criteria
1. Men and women (aged 65 to 85)
2. Healthy
3. Poor vitamin B12 status (plasma B12 <250 pmol/l, urinary MMA > 1.5 µmol/mmol creatinine)

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
100

Key exclusion criteria
1. Severe cognitive impairment
2. Gastric or ileal surgery
3. Regular vitamin B12 injections

Date of first enrolment
01/01/2010

Date of final enrolment
30/12/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Professor of Nutritional Biochemistry
Sheffield
United Kingdom
S10 2RX

Sponsor information

Organisation
University of Sheffield (UK)

Sponsor details
Western Bank
Sheffield
England
United Kingdom
S10 2TN

Sponsor type
University/education

Website
http://www.sheffield.ac.uk

ROR
https://ror.org/05krs5044

Funder(s)

Funder type
Government

Funder Name
Food Standards Agency (FSA) (UK)

Alternative Name(s)
The Food Standards Agency, FSA

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

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	01/02/2013		Yes	No