

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

Submission date
07/05/2010

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
14/07/2010

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
15/03/2013

Condition category
Nutritional, Metabolic, Endocrine

☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Hilary Powers

Contact details
Professor of Nutritional Biochemistry
Human Nutrition Unit
University of Sheffield
The School of Medicine
Beech Hill Road
Sheffield
United Kingdom
S10 2RX

Additional identifiers

Protocol serial number
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)

Primary study design

Interventional

Study design

Interventional 4 arm double blind randomised placebo controlled parallel group trial

Study type(s)

Screening

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(s)

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

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Senior

Sex

All

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

United Kingdom

England

Study participating centre

Professor of Nutritional Biochemistry

Sheffield

United Kingdom

S10 2RX

Sponsor information

Organisation

University of Sheffield (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

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