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Plasma homocysteine response to folic acid intervention

Submission date	Recruitment status	[_] Prospectively registered
29/01/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
05/03/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
02/02/2011	Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Mary Ward

Contact details
Northern Ireland Centre for Food and Health
School of Biomedical Sciences
University of Ulster
Coleraine
United Kingdom
BT521SA
+44 (0)28 7032 3076
mw.ward@ulster.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A dose finding trial in ischaemic heart disease patients and healthy controls to determine whether chronic exposure to low-dose folic acid can lower homocysteine

Study objectives
Low dose folic acid (0.2 mg/d) administered chronically will significantly lower plasma homocysteine in ischaemic heart disease (IHD) patients and healthy age-sex matched controls. Previous studies may have overestimated the folic acid dose required to lower homocysteine because of too-short an intervention period to observe the full extent of the response to low folic acid doses and concluded that much higher doses were required for maximal homocysteine-lowering.

If the hypothesis is confirmed the findings will have important implications for governments worldwide currently considering food fortification with folic acid, which although primarily aimed at reducing neural tube defects (NTDs), is expected to have important benefits in terms of the primary and secondary prevention of cardiovascular disease (CVD) via a homocysteine-lowering effect.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study was approved by the University of Ulster Ethics committee in March 2000 (ref: 01/17).

Study design
Double-blinded, randomised, placebo controlled dose finding trial with folic acid

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Ischaemic heart disease

Interventions

In both IHD and healthy control groups, participants were stratified into tertiles of homocysteine concentration (from the screening blood sample). Subjects in each stratum were then randomised to receive placebo, 0.2, 0.4 or 0.8 mg/d folic acid for a total intervention period of 26 weeks. To maximise compliance, vitamins were distributed every three weeks to the participants homes in seven-day pillboxes. The pillboxes were then collected and any unused pills recorded in order to monitor compliance.

Total intervention period of 26 weeks for all treatment arms.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Folic acid

Primary outcome measure
Plasma homocysteine, measured at baseline, 6 weeks and 12 weeks in a subset, and at 26 weeks.

Secondary outcome measures
1. Serum folate, measured at baseline and at 26 weeks
2. Erythrocyte glutathione reductase activity coefficient (EGRac): an indicator of riboflavin status), measured at baseline
2. Plasma pyridoxal phosphate: an indicator of vitamin B6 status, measured at baseline
3. Serum vitamin B12, measured at baseline

Overall study start date
31/03/2001

Completion date
31/12/2004

Eligibility

Key inclusion criteria
1. Male and female, any age
2. IHD Patients:
2.1. Proven myocardial infarction more than three months previously
2.2. IHD on coronary angiography
2.3. A clinical diagnosis of angina confirmed by electrocardiogram (ECG)
3. Control subjects: healthy subjects age- and sex-matched with the IHD group from the local community

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
n = 200 (100 patients, 100 controls)

Key exclusion criteria
1. IHD patients:
1.1. History of diabetes
1.2. Hepatic or renal disease
1.3. Haematological disorders
1.4. Use of B-vitamin supplements or use of medication known to interfere with folate metabolism
2. Healthy controls in addition had no history of CVD

Date of first enrolment
31/03/2001

Date of final enrolment
31/12/2004

Locations

Countries of recruitment
Northern Ireland

United Kingdom

Study participating centre
Northern Ireland Centre for Food and Health
Coleraine
United Kingdom
BT521SA

Sponsor information

Organisation
University of Ulster (UK)

Sponsor details
c/o Mary Ward
School of Biomedical Sciences
Cromore Road
Coleraine
Northern Ireland

United Kingdom
BT52 1SA
+44 (0)28 7032 3076
mw.ward@ulster.ac.uk

Sponsor type
University/education

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

ROR
https://ror.org/01yp9g959

Funder(s)

Funder type
Charity

Funder Name
Northern Ireland Chest Heart and Stroke Association (UK)

Alternative Name(s)
NICHS

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

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	01/01/2011		Yes	No