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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

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## Additional identifiers

## 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

## Study type(s)
Treatment

## 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(s)

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

### Key secondary outcome(s))
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

### 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

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
All

### 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**
United Kingdom

Northern Ireland

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

# Sponsor information

**Organisation**
University of Ulster (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

## 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 |