Folate Intervention in Non-ST elevation myocardial infarction and unstable angina: a randomised placebo-controlled trial

Submission date Recruitment status Prospectively registered 26/06/2007 No longer recruiting [] Protocol Statistical analysis plan Registration date Overall study status 30/07/2007 Completed [X] Results [] Individual participant data Last Edited Condition category 06/07/2009 Circulatory System

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number N/A

Study information

Scientific Title

Acronym

FINEST

Study objectives

Homocysteine is a sulphur-containing amino acid derived from the demethylation of methionine. Increased plasma homocysteine level has been recognised as a risk factor for cardiovascular diseases. Non-ST Elevation Myocardial Infarction (NSTEMI) and Unstable Angina (UA) belong to the spectrum of Acute Coronary Syndromes (ACS) that implies partial occlusion of the coronaries leading to ischaemic events. Unstable angina and NSTEMI have high recurrence rates for ACS and mortality six months after the event. Blood homocysteine levels are higher in patients with unstable angina, and it has been implicated to poorer outcomes and greater myocardial injury. Low homocysteine level confers better long-term outcomes among patients with coronary heart disease.

Folic acid is a potent homocysteine-lowering agent. It is used in several clinical trials to assess reduction of outcomes in subjects with cardiovascular disease.

Hypothesis:

Homocysteine-lowering could reduce subsequent clinical events, such as mortality and the composite outcomes of mortality, nonfatal acute coronary syndrome and other serious rehospitalisation in people with UA or NSTEMI.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Committee on Research Implementation and Development (CRID) (presently Research Implementation and Development Office [RIDO]) of the College of Medicine, University of the Philippines Manila, approved on October 25, 2002.

Study design

The study is a randomised placebo-controlled trial. The participants are recruited from five medical centres. The participants, researchers and assessors were blinded to treatment assignment.

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Acute Coronary Syndromes (ACS)

Interventions

Active group (116 participants): A once daily oral supplement of 1 mg folic acid, 400 µg vitamin B12, and 10 mg vitamin B6 for six months

Placebo group (124 participants): Once daily oral placebo supplement for six months

The participants were followed up for six months.

Intervention Type

Supplement

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Folic acid, vitamin B12, vitamin B6

Primary outcome(s)

- 1. All-cause mortality
- 2. Composite outcomes of mortality, nonfatal acute coronary syndromes and serious rehospitalisation

Outcomes measured every six months for three years, timepoints were as follows:

31st January 2004

31st July 2004

31st January 2005

31st July 2005

31st January 2006

31st July 2006

Key secondary outcome(s))

No secondary outcome measures

Completion date

15/08/2006

Eligibility

Key inclusion criteria

Subjects with unstable angina (intermediate- and high-risk) or NSTEMI with an onset in the past two weeks were screened for inclusion for the study. Participants should be more than 18 years of age upon inclusion, either male or female.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

The exclusion criteria include the following:

- 1. Haemodynamic instability (cardiogenic shock, ongoing chest pain, unresolved and new onset end-organ damage, and unstable congestive heart failure in the past two weeks)
- 2. Significant liver disease (classical signs and symptoms, or three times the upper limit of normal in liver enzymes, or a deranged Prothrombin Time [PT] 1.5 x normal not explained by anticoagulant intake)
- 3. Significant renal disease (with creatinine levels more than 180 µmol/dl or requiring dialysis)
- 4. Haemoglobin less than 1 g/dl
- 5. High output failure
- 6. Could not provide adequate self-care
- 7. Malignancy or any terminal illness
- 8. Pregnancy
- 10. Could not provide independent informed consent
- 11. Living outside Metro Manila or the adjacent provinces of Cavite and Rizal

Date of first enrolment

15/08/2003

Date of final enrolment

15/08/2006

Locations

Countries of recruitment

Philippines

Study participating centre 1148 Orani Street

Valenzuela City Philippines 1440

Sponsor information

Organisation

Philippine Council for Health Research and Development (PCHRD) (Philippines)

Funder(s)

Funder type

Government

Funder Name

The Department of Science and Technology (Philippines) - Grants in Aid program (DOST-GIA)

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	01/01/2009		Yes	No