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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 re-hospitalisation 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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)

Treatment

Participant information sheet

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 measure
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

Secondary outcome measures
No secondary outcome measures

Overall study start date
15/08/2003

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
250

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
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Sponsor information

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

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Sponsor type
Government

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Funder(s)

Funder type
Government

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

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	01/01/2009		Yes	No