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Heart Outcomes Prevention Evaluation-2 (HOPE-2) study

Submission date 05/09/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 05/09/2005	**Overall study status** Completed	
Last Edited 03/08/2009	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.phri.ca

Contact information

Type(s)
Scientific

Contact name
Dr Eva Lonn

Contact details
HGH-McMaster Clinic
237 Barton Street East
Room 254
Hamilton
Canada
L8L 2X2
+1 905 526 0970
lonnem@mcmaster.ca

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00106886

Secondary identifying numbers
MCT-15428

Study information

Scientific Title

Acronym
HOPE-2

Study objectives
1. To evaluate whether prolonged therapy with folic acid and vitamins B6 and B12 compared to placebo reduces the risk of cardiovascular death, myocardial infarction (MI) and stroke (major fatal and non-fatal cardiovascular [CV] events)
2. To evaluate the effects of the study intervention on major fatal and non-fatal CV and revascularisation procedures and on total important ischaemic events

Ethics approval required
Old ethics approval format

Ethics approval(s)
Hamilton Health Sciences Corporation and McMaster University approved on the 17th November 1999.

Study design
Randomised controlled trial

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
Cardiovascular disease, myocardial infarction (MI), stroke, cancer

Interventions
Combination pill containing: Folic acid 2.5 mg, vitamin B6 50 mg, vitamin B12 1 mg, or placebo

Intervention Type

Supplement

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Folic acid, vitamins B6 and B12

Primary outcome measure
The composite of cardiovascular death, myocardial infarction (MI) and stroke.

Secondary outcome measures
1. Total major ischaemic events, including CV death, MI, stroke, hospitalisations for unstable angina and revascularisations
2. Total mortality
3. Hospitalisation for unstable angina (UA)
4. Hospitalisation for congestive heart failure (CHF)
5. Revascularisation procedures
6. Incident cancer
7. Cancer death

Overall study start date
01/04/1999

Completion date
31/03/2006

Eligibility

Key inclusion criteria
1. Women and men 55 years of age or over with established CVD and at high risk for future fatal and nonfatal CV events defined as:
1.1. Documented coronary artery disease (CAD)
1.2. Documented peripheral vascular disease (PVD)
1.3. Documented cerebrovascular disease
1.4. Diabetes with one of the following additional cardiovascular risk factors:
1.4.1. Hypertension (blood pressure [BP] greater than 160 mmHg systolic or greater than 90 mmHg diastolic or on treatment)
1.4.2. Total cholesterol greater than 5.2 mmol/l (greater than 200 mg/dl)
1.4.3. High density lipoprotein (HDL) cholesterol less than 0.9 mmol/l (3.5 mg/dl)
1.4.4. Current cigarette smoker
1.4.5. Any evidence of previous vascular disease
2. Provision of informed consent

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
5552

Key exclusion criteria
1. Current use of any vitamin supplements containing folic acid greater than 200 µg/day. Patients taking such vitamin supplements can be asked if they agree to discontinue these supplements. If they agree they can be randomised to the study.
2. Known previous adverse reactions to folic acid, vitamin B6 or B12
3. Planned cardiac, peripheral or cerebrovascular revascularization, defined as a decision taken by the patient and his or her physician(s) to perform surgical or percutaneous transluminal revascularisation within the next 6 months
4. Haemodynamically significant primary valvular outflow tract obstruction (e.g. mitral stenosis, asymmetric septal hypertrophy, malfunctioning prosthetic valve)
5. Constrictive pericarditis
6. Complex congenital heart disease
7. Syncopal episodes presumed to be due to uncontrolled life-threatening arrhythmias (asymptomatic arrhythmias including ventricular tachycardia are not exclusion criteria)
8. Uncontrolled hypertension
9. Cor pulmonale
10. Heart transplant recipient
11. Other important non-cardiovascular disease(s) expected to limit compliance and/or impact on patients ability to complete the study, such as: history of alcohol or drug abuse, psychiatric disorders, senility, severe physical disability, illnesses including terminal stage cancer and other major systemic illnesses expected to limit the patients ability to comply with the study protocol and to complete the study

Date of first enrolment
01/04/1999

Date of final enrolment
31/03/2006

Locations

Countries of recruitment
Canada

Study participating centre
HGH-McMaster Clinic
Hamilton
Canada
L8L 2X2

Sponsor information

Organisation
McMaster University (Canada)

Sponsor details
Office of the Associate Dean
Research
McMaster University
Faculty of Health Sciences
1200 Main Street West
Room HSC-3N8
Hamilton
Canada
L8N 3Z5

Sponsor type
University/education

Website
http://www.mcmaster.ca/

ROR
https://ror.org/02fa3aq29

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-15428)

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	13/04/2006		Yes	No
Results article	results	05/06/2007		Yes	No
Results article	results	01/04/2009		Yes	No