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Homocysteine lowering and atherosclerosis reduction trial (HART)

Submission date	Recruitment status	[_] Prospectively registered
26/09/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
26/09/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
09/08/2019	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
NCT00217178

Secondary identifying numbers
MCT-44159

Study information

Scientific Title
Correlations between plasma homocysteine and folate concentrations and carotid atherosclerosis in high-risk individuals

Acronym
HART

Study objectives
To evaluate whether combined therapy with folic acid 2.5 mg/day, vitamin B6 50 mg/day and vitamin B12 1 mg/day versus placebo reduces the rate of atherosclerosis, as evaluated by quantitative B-mode carotid ultrasound (US).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Board of McMaster University approved on the 2nd February 2000

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
Atherosclerotic cardiovascular disease (CVD)

Interventions
Intervention:
Combination of folic acid 2.5 mg, vitamin B6 50 mg and vitamin B12 1.0 mg daily, which is expected to reduce tHcy by about one quarter to one third, even in persons who are not frankly deficient and extremely safe.

Control:
Placebo.

Trial details received: 12 Sept 2005

Intervention Type
Supplement

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Vitamins

Primary outcome measure
The change over time (annualised progression slope) in the mean maximum intima-media thickness (IMT (the mean maximum IMT slope), defined as the average of the maximum IMT across the 12 preselected carotid arterial segments.

Secondary outcome measures
1. The change over time (annualised progression slope) in the single maximum IMT amongst any of the same preselected carotid artery segments, i.e., the haemodynamically most important lesson
2. The effect of folate and vitamins B6, B12 therapy on clinical outcomes

Overall study start date
01/04/2000

Completion date
31/10/2005

Eligibility

Key inclusion criteria
1. Women and men aged greater than or equal to 55 years at high risk for cardiovascular (CV) events with:
1.1. Documented (CAD):
1.1.1. History of prior myocardial infarction (MI)
1.1.2. Stable or unstable angina with documented multivessel coronary artery disease (CAD) or strongly positive stress test
1.1.3. Multivessel CAD and percutanerous transluminal coronary angioplasty (PTCA) greater than or equal to 6 months prior to randomisation
1.1.4. Multivessel CABG greater than or equal to 4 years prior to randomisation
1.1.5. Multivessel CAD on angiography
1.2. Documented peripheral vascular disease (PVD):
1.2.1. Previous limp bypass surgery and/or previous peripheral percutaneous transluminal angioplasty and/or previous limp or foot amputation due to PVD
1.2.2. History of intermittent claudication with ankle/arm blood pressure ratio of greater than or equal to 0.80 or with significant arterial stenosis on angiography
1.3. Documented cerebrovascular disease: history of previous ischaemic stroke
1.4. Diabetes mellitus with greater than or equal to one additional major CV risk factor(s)
2. Provision of informed consent
3. Adequate baseline carotid US examination

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
921

Key exclusion criteria
1. Current use of folic acid supplements greater than 200 mg/day
2. Known previous adverse reactions to folic acid, vitamin B6 or B12
3. Planned cardiac, peripheral or cerebrovascular surgery

Date of first enrolment
01/04/2000

Date of final enrolment
31/10/2005

Locations

Countries of recruitment
Canada

Study participating centre
HGH-McMaster Clinic
Hamilton
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Sponsor information

Organisation
McMaster University (Canada)

Sponsor details
Office of the Associate Dean Research
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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-44159)

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	baseline results	01/11/2008	09/08/2019	Yes	No