

Homocysteine lowering and atherosclerosis reduction trial (HART)

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|----------------------------------------|---------------------------------------------------|---------------------------------------------------------------------------------------------------|
| Submission date 26/09/2005 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 26/09/2005 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 09/08/2019 | Condition category Circulatory System | <input type="checkbox"/> Individual participant data |

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 lesion
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 percutaneous 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 limb bypass surgery and/or previous peripheral percutaneous transluminal angioplasty and/or previous limb 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

Canada

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Sponsor information**Organisation**

McMaster University (Canada)

Sponsor details

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Faculty of Health Sciences

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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 |