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Pilot study for CHAOS-Two (Cambridge Heart Anti-Oxidant study: trial with other vitamins)

Submission date	Recruitment status	[ ] Prospectively registered
23/01/2004	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
23/01/2004	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
30/04/2018	Circulatory System	[ ] Record updated in last year

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
Brown HSR/06/97

Study information

Scientific Title

Pilot study for CHAOS-Two (Cambridge Heart Anti-Oxidant study: trial with other vitamins)

Acronym
CHAOS-Two

Study objectives
The overall aim of CHAOS-Two is to determine whether folic acid reduces the incidence of myocardial infarction. The principle current hypothesis on which to base expectation of benefit is a well documented effect of folic acid to reduce plasma levels of the amino acid, homocysteine, which has been found in several prospective and case-control studies to be a major risk factor for atherosclerotic diseases. CHAOS-Two should thus provide a test of the homocysteine hypothesis. However, an additional pathway through which folic acid may be beneficial is the so-called salvage pathway to synthesis of the co-factor, tetrahydrobiopterin, required for Nitric Oxide (NO) synthesis. The principle requirement of the pilot study is to permit calculation of numbers required for the main study, using the relative risk of homocysteine in the epidemiological studies, and the average difference after 1 year between homocysteine levels in the folate and placebo groups. The pilot will also establish whether folic acid had the additional action via NO.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Randomised placebo controlled trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Heart disease

Interventions
1. Folate 5 mg
2. Placebo

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
1. Main Study
1.1. Fatal or non-fatal myocardial infarction.

2. Pilot Study
2.1. Percentage of patients with B12 deficiency on entry despite normal Hb and MCV, and patients becoming B12 deficient at follow-ups.
2.2. Percentage change in plasma homocysteine and plasma tetrahydrobiopterin in response to folic acid, and variation in these over one year.
2.3. Compliance with treatment addeddes from rise in rbc folate in active group.
2.4. Estimate of number of eligible patients likely to be recruited annually.

Key secondary outcome(s)
Not provided at time of registration

Completion date
01/07/1999

Eligibility

Key inclusion criteria
1. Patients admitted for coronary angiograph
2. Stable angina
3. Positive coronary angiogram

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Key exclusion criteria
Patients with a macrocytic anaemia (Hb <10, mean cell volume [MCV] >100) will be excluded from the pilot unless their serum B12 is normal. To be revised if indicated by follow-up results of Hb and B12 pilot.

Date of first enrolment
01/07/1997

Date of final enrolment
01/07/1999

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Cambridge
Cambridge
United Kingdom
CB2 2QQ

Sponsor information

Organisation
NHS R&D Regional Programme Register - Department of Health (UK)

Funder(s)

Funder type
Government

Funder Name
NHS Executive Eastern (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration