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

Contact name

Prof Morris Brown

Contact details

University of Cambridge Clinical Pharmacology Unit Level 6, ACCI Hills Road Addenbrooke's Hospital Cambridge United Kingdom CB2 2QQ +44 (0)1223 336743 mjb14@medschl.cam.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Study design

Randomised placebo controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Prevention

Participant information sheet

Health condition(s) or problem(s) studied

Heart disease

Interventions

- 1. Folate 5 mg
- 2. Placebo

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

- 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.

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/07/1997

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

Age group

Not Specified

Sex

Not Specified

Target number of participants

Not provided at time of registration

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

England

United Kingdom

Study participating centre University of Cambridge

Cambridge United Kingdom CB2 2QQ

Sponsor information

Organisation

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

Sponsor details

The Department of Health Richmond House 79 Whitehall London United Kingdom SW1A 2NL +44 (0)20 7307 2622 dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

http://www.doh.gov.uk

Funder(s)

Funder type

Government

Funder Name

NHS Executive Eastern (UK)

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