

Cambridge Heart Antioxidant Study

Submission date 23/01/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 23/01/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 20/10/2010	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English Summary

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Nigel Stephens

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Randomised controlled trial of vitamin E in patients with coronary disease: Cambridge Heart Antioxidant Study (CHAOS)

Acronym

CHAOS

Study hypothesis

The hypothesis tested was: treatment with a high dose of alpha-tocopherol would reduce subsequent risk of myocardial infarction (MI) and cardiovascular death in patients with established ischaemic heart disease

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

Condition

Cardiovascular diseases: Heart disease

Interventions

Alpha-tocopherol 800 IU daily for first 546 patients, alpha-tocopherol 400 IU daily for remainder versus placebo

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Cardiovascular death and non-fatal MI as well as non-fatal MI alone

Secondary outcome measures

Not provided at time of registration

Overall study start date

10/10/1992

Overall study end date

18/06/1995

Eligibility

Participant inclusion criteria

Patients with angiographically proven coronary atherosclerosis

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

Added December 2008

Participant exclusion criteria

Not provided at time of registration

Recruitment start date

10/10/1992

Recruitment end date

18/06/1995

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Cardiology Department

Middlesex

United Kingdom

HA1 3UJ

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	23/03/1996		Yes	No
Results article	results	30/01/1999		Yes	No