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Heart protection study

Submission date 06/04/2000	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 06/04/2000	**Overall study status** Completed	
Last Edited 30/07/2012	**Condition category** Circulatory System	

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
G9123430

Study information

Scientific Title

Study objectives
1. Providing unequivocal evidence about the effects of cholesterol-lowering drug therapy with simvastatin on total mortality among high-risk patients
2. Demonstrating reliably the effects on coronary heart disease (CHD) within several subgroups where there is still uncertainty (e.g. women, elderly, below-average cholesterol, hypertensive)

3. Providing reliable information about effects on non-cardiac mortality and morbidity (i.e. cancer, trauma, etc.), on vascular surgery and other hospitalisations and any major side-effects
4. Assessing effects of vitamin supplementation on CHD

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 factorial design trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Coronary heart disease (CHD)

Interventions
Patients were randomised in a 2 x 2 factorial design to receive:
1. 40 mg simvastatin daily or matching placebo tablets
2. Antioxidant vitamins (vitamins E, C and beta-carotene) or matching placebo capsules

Treatment duration was for five years.

Intervention Type
Supplement

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Simvastatin, vitamins E and C, beta-carotene

Primary outcome(s)
1. Total mortality and cause-specific mortality for statin comparison
2. Total CHD and fatal CHD for vitamin comparison
3. Major vascular events and total CHD for subgroups

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

Completion date
01/10/2001

Eligibility

Key inclusion criteria
1. Patients at high risk of CHD (e.g., because of history of vascular disease or diabetes)
2. Without clear indication for or contra-indication to statin
3. Male and female adults
4. Non-fasting blood total cholesterol concentrations of at least 3.5 mmol/L (135 mg/dL)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. The patient's doctor considered statin therapy to be clearly indicated or contra-indicated
2. A past history of: stroke, myocardial infarction or angina hospitalisation within the previous six months
3. Chronic liver disease or evidence of abnormal liver function
4. Severe renal disease or evidence of substantially impaired renal function
5. Inflammatory muscle disease or evidence of muscle problems
6. Concurrent treatment with cyclosporin, fibrates or high-dose niacin
7. Child-bearing potential
8. Severe heart failure
9. Life-threatening conditions other than vascular disease or diabetes (including any cancer except non-melanoma skin cancer)
10. Any other condition that might limit long-term compliance

Date of first enrolment
01/01/1994

Date of final enrolment
01/10/2001

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Clinical Trial Service Unit
Oxford

United Kingdom
OX2 6HE

Sponsor information

Organisation
Medical Research Council (MRC) (UK)

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

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	16/03/2005		Yes	No

Results article	results	23/01/2007	Yes	No
Results article	results	31/03/2009	Yes	No
Results article	genetic variant results	01/02/2011	Yes	No
Results article	results	05/02/2011	Yes	No
Results article	results	17/05/2011	Yes	No
Results article	results	22/05/2012	Yes	No
Results article	sub-study results on cholesterol and risk of vascular events	22/05/2012	Yes	No