ISRCTN48489393 https://doi.org/10.1186/ISRCTN48489393

# Heart protection study

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

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

**Contact name**
Dr Rory Collins

**Contact details**
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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

### Study design
Randomised placebo controlled factorial design trial

### Primary study design
Interventional

### 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, 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 | 23/01 | | | |

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|---|---|---|---|---|---|
| Results article | | /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 |
| Participant information sheet | Participant information sheet | 11/11 /2025 | 11/11 /2025 | No | Yes |