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Study of the Effectiveness of Additional Reductions in Cholesterol and Homocysteine

Submission date 15/08/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 09/09/2005	**Overall study status** Completed	
Last Edited 31/08/2022	**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

ClinicalTrials.gov (NCT)
NCT00124072

Protocol serial number
CTSU SEARCH1

Study information

Scientific Title
Study of the Effectiveness of Additional Reductions in Cholesterol and Homocysteine

Acronym
SEARCH

Study objectives
Do larger reductions in blood cholesterol produce larger, and worthwhile, reductions in cardiovascular risk, and does homocysteine-lowering with folic acid and vitamin B12 reduce cardiovascular risk?

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

Study type(s)
Treatment

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

Interventions
Simvastatin 80 mg versus 20 mg daily, and separately folic acid 2 mg plus 1 mg vitamin B12 daily or matching placebo tablets.

Intervention Type
Supplement

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Simvastatin, folic acid and vitamin B12

Primary outcome(s)
Major vascular events (MVEs) during the scheduled treatment period

Key secondary outcome(s))
MVEs separately during the first year and in the later years of the study, MVEs in patients subdivided by pre-randomisation lipid levels, MVEs in the presence and absence of the other randomised treatments, major coronary events, total strokes

Completion date
31/12/2007

Eligibility

Key inclusion criteria
Men and women who have survivied a heart attack and in whom statin therapy is indicated.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
12064

Key exclusion criteria
Age under 18 years or over 80 at invitation, contraindications to either study drug, other predominant medical problem.

Date of first enrolment
30/07/1998

Date of final enrolment
31/12/2007

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Clinical Trial Service Unit
Oxford
United Kingdom
OX3 7LF

Sponsor information

Organisation
University of Oxford (UK)

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Industry

Funder Name
A grant to Oxford University from Merck and Co.

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

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	21/08/2008		Yes	No
Results article	results	23/06/2010		Yes	No
Basic results			26/09/2019	No	No