ISRCTN47214063 https://doi.org/10.1186/ISRCTN47214063

Simvastatin (20 mg) vs ezetimibe (10 mg) plus simvastatin (20 mg) in subjects with hypercholesterolaemia and coronary heart disease (CHD)

Submission date 06/07/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 13/08/2004	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 25/11/2013	**Condition category** Circulatory System	[_] Individual participant data [_] Record updated in last year

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
P03435

Study information

Scientific Title

Study objectives
Not provided at time of registration

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)
Not Specified

Health condition(s) or problem(s) studied
Hypercholesterolaemia and CHD

Interventions
Double-blind study involving 6 weeks treatment with a once daily dose of simvastatin (20 mg) plus either ezetimibe (10 mg) or matching ezetimibe placebo. Blood samples will be collected prior to treatment to use as a baseline and at the end of the 6 week treatment period to determine the effect of the treatments on the lipid profiles. These pre and post treatment blood samples will also be analysed for haematology and clinical chemistry parameters for safety assessment purposes. The objective of the study is to compare the post treatment lipid results (primarily LDL-C) with the baseline values between the two treatment groups. In addition, the usual safety assessments (i.e. adverse events) and details of concomitant medications etc. will be collected during the study.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Not provided at time of registration

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

Completion date
31/05/2005

Eligibility

Key inclusion criteria

Male or female subjects aged 18-75 years with screening low-density lipoprotein cholesterol (LDL-C) between 3.3 and 4.9 mmol/l

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
75 years

Sex
All

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/04/2000

Date of final enrolment
31/05/2005

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Schering-Plough Ltd
Welwyn Garden City
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AL7 1TW

Sponsor information

Organisation
Schering-Plough UK Ltd

ROR
https://ror.org/00148fb49

Funder(s)

Funder type
Industry

Funder Name
Schering-Plough UK Ltd

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration