

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	<input type="checkbox"/> Prospectively registered
Registration date 13/08/2004	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 25/11/2013	Condition category Circulatory System	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

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 measure

Not provided at time of registration

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/04/2000

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

Age group

Adult

Lower age limit

18 Years

Upper age limit

75 Years

Sex

Both

Target number of participants

Not provided at time of registration

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

England

United Kingdom

Study participating centre

Schering-Plough Ltd

Welwyn Garden City

United Kingdom

AL7 1TW

Sponsor information

Organisation

Schering-Plough UK Ltd

Sponsor details

Schering-Plough House

Shire Park

Welwyn Garden City

United Kingdom

AL7 1TW

Sponsor type

Not defined

ROR

<https://ror.org/00148fb49>

Funder(s)

Funder type

Industry

Funder Name

Schering-Plough UK Ltd

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