ISRCTN18808154 https://doi.org/10.1186/ISRCTN18808154

Atorvastatin (10 mg) vs ezetimibe (10 mg) plus atorvastatin (10 mg) in hypercholesterolaemia and coronary heart disease (CHD)

Submission date
06/07/2004

Recruitment status
No longer recruiting

Registration date
13/08/2004

Overall study status
Completed

Last Edited
15/05/2014

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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
P03434

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 atorvastatin (10 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
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
atorvastatin, ezetimibe

Primary outcome(s)
Not provided at time of registration

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

Completion date
31/12/2004

Eligibility

Key inclusion criteria
Male or female subjects aged 18-75 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
01/01/2004

Date of final enrolment
31/12/2004

Locations

Countries of recruitment
United Kingdom

England

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

Sponsor information

Organisation
Schering-Plough UK Ltd

ROR
https://ror.org/00148fb49

Funder(s)

Funder type
Industry

Funder Name
Schering-Plough Ltd (UK)

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	01/04/2007		Yes	No