

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

|                                        |                                                                |                                                      |
|----------------------------------------|----------------------------------------------------------------|------------------------------------------------------|
| <b>Submission date</b><br>06/07/2004   | <b>Recruitment status</b><br>No longer recruiting              | <input type="checkbox"/> Prospectively registered    |
| <b>Registration date</b><br>13/08/2004 | <b>Overall study status</b><br>Completed                       | <input type="checkbox"/> Protocol                    |
| <b>Last Edited</b><br>15/05/2014       | <b>Condition category</b><br>Nutritional, Metabolic, Endocrine | <input type="checkbox"/> Statistical analysis plan   |
|                                        |                                                                | <input checked="" type="checkbox"/> Results          |
|                                        |                                                                | <input type="checkbox"/> Individual participant data |

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Dr Paul Quartey

### Contact details

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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

**Primary study design**

Interventional

**Study design**

Randomised controlled trial

**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? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results | 01/04/2007   |            | Yes            | No              |