A Study to Determine the Number of Patients Who Reach Optimal Cholesterol Levels on Each of Three Different Treatments (0653A-121)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

Information provided by (Responsible Party):
Merck Sharp & Dohme Corp.

ClinicalTrials.gov Identifier:
NCT00462748

First received: April 18, 2007
Last updated: October 9, 2015
Last verified: October 2015
History of Changes

Purpose

To evaluate the percentage of patients with either established cardiovascular disease (CVD), at "high risk" of developing CVD or with diabetes who are on simvastatin 40mg, with fasting LDL-C > 2mmol/l, who are able to attain the recommended LDL-C target of < 2mmol/l following 6 weeks treatment with either ezetimibe/simvastatin 10/40mg, atorvastatin 40mg or rosuvastatin 10mg.

Condition	Intervention	Phase
Hypercholesterolemia	Drug: ezetimibe (+) simvastatin Drug: Comparator: atorvastatin Drug: Comparator: rosuvastatin	Phase 3

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Parallel Assignment
Masking: Double Blind (Subject, Investigator)
Primary Purpose: Treatment

Official Title: A MC, DB, Rand, Study to Evaluate Efficacy, Safety and Tolerability of Eze/Simva 10/40 mg, Atorva 40 mg, Rosuva 10 mg in Achieving LDL-C <2 mmol/l in Pts With CVD...on Simva 40 mg With LDL-C ³2 mmol/l

Resource links provided by NLM:

MedlinePlus related topics: Cholesterol

Drug Information available for: Simvastatin Atorvastatin Atorvastatin calcium Rosuvastatin calcium Ezetimibe Rosuvastatin Atorvastatin calcium trihydrate

U.S. FDA Resources

Further study details as provided by Merck Sharp & Dohme Corp.:

Primary Outcome Measures:

- Percentage of Patients Achieving a Target of Fasting LDL-C of <2mmol/l at Study End [Time Frame: 6 Weeks]
  [Designated as safety issue: No]

  Fasting LDL-C was the primary efficacy variable. The primary efficacy analysis was based on the proportion of patients achieving a target of <2mmol/l in fasting LDL-C at study end.

Enrollment:	786
Study Start Date:	March 2007
Study Completion Date:	June 2008
Primary Completion Date:	June 2008 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: 1 Arm 1: Drug	Drug: ezetimibe (+) simvastatin ezetimibe (+) simvastatin 10/40mg. once daily tablet formulation, all tablet form, taken orally, cholesterol lowering medication. Other Name: MK0653A
Active Comparator: 2 Arm 2: Active comparator	Drug: Comparator: atorvastatin atorvastatin 40mg. once daily tablet formulation, all tablet form, taken orally Other Name: atorvastatin
Active Comparator: 3 Arm 3: Active comparator	Drug: Comparator: rosuvastatin rosuvastatin 10 mg. once daily tablet formulation, all tablet form, taken orally. Other Name: rosuvastatin

Eligibility

Ages Eligible for Study:	18 Years and older (Adult, Senior)
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Patient Is Male Or Female And Aged Over 18
- Patient Provides Written Informed Consent
- Patient Has A Fasting Ldl-C Level >2mmol/L At Both Visit 1 And Again At Visit 2
- Patient Has Established Cvd, Diabetes Or At "High Risk" Of Cvd (>20 % Risk Over 10 Years, Framingham Scale)
- Patient Has Taken Simvastatin 40mg Continuously For The Past 6 Weeks
- Patient Has A Fasting Triglyceride Level Of <3.7mmol/L
- Patient Has Hba1c <9% At Visit 1
- Patient Is 75% Compliant With Medication Between Visit 1 And Visit 2

Exclusion Criteria:

- Patient Is Hypersensitive To Any Of The Study Medications Or Their Components
- Patient Has A History Of, Or Active Liver Disease (Persistent Elevation Of Alt / Ast (>3xuln)
- Patient Is Pregnant, Lactating, Or A Female Patient Of Childbearing Potential Not Using Adequate Contraception
- Patient Has Severe Renal Impairment: Creatinine Clearance <30ml/Min (Cockcroft-Gault Equation) (In Patients With Moderate Renal Impairment: <60ml/Min, The Dose Of Rosuvastatin Will Be 5mg In Line With The Spc)
- Patient Has Uncontrolled Endocrine Or Metabolic Disease Known To Influence Serum Lipids Or Lipoproteins (I.E. Secondary Causes Of Hyperlipidaemia Such As Hypothyroidism Or Hyperthyroidism)

- Patient Has A Recent History Of, Or Current, Alcohol Abuse
- Patient Has Ck >10 X Uln At Visit 1 Or Visit 2
- Patient Has Fasting Ldl-C >4.2mmol/L
- Patient Has Any Acute Or Serious Condition, Or History Suggestive Of Myopathy Or Predisposing To The Development Of Renal Failure Secondary To Rhabdomyolysis (E.G. Sepsis, Hypotension, Major Surgery, Trauma, Severe Metabolic, Severe Endocrine And Electrolyte Disorders Or Uncontrolled Seizures)

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT00462748

Sponsors and Collaborators

Merck Sharp & Dohme Corp.

Investigators

Study Director: Medical Monitor Merck Sharp & Dohme Corp.

More Information

Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

McCormack T, Harvey P, Gaunt R, Allgar V, Chipperfield R, Robinson P; IN-PRACTICE study. Incremental cholesterol reduction with ezetimibe/simvastatin, atorvastatin and rosuvastatin in UK General Practice (IN-PRACTICE): randomised controlled trial of achievement of Joint British Societies (JBS-2) cholesterol targets. Int J Clin Pract. 2010 Jul;64(8):1052-61. doi: 10.1111/j.1742-1241.2010.02429.x. Epub 2010 May 12.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00462748 History of Changes
Other Study ID Numbers:	**0653A-121** MK**0653A-121** 2007_013
Study First Received:	April 18, 2007
Results First Received:	May 7, 2009
Last Updated:	October 9, 2015
Health Authority:	United Kingdom: Medicines and Healthcare Products Regulatory Agency

Additional relevant MeSH terms:

Hypercholesterolemia	Ezetimibe
Hyperlipidemias	Anticholesteremic Agents
Dyslipidemias	Hypolipidemic Agents
Lipid Metabolism Disorders	Antimetabolites
Metabolic Diseases	Molecular Mechanisms of Pharmacological Action
Atorvastatin Calcium	Lipid Regulating Agents
Simvastatin	Hydroxymethylglutaryl-CoA Reductase Inhibitors
Rosuvastatin Calcium	Enzyme Inhibitors

ClinicalTrials.gov processed this record on October 12, 2016

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Results First Received: May 7, 2009

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Treatment
Condition:	Hypercholesterolemia
Interventions:	Drug: ezetimibe (+) simvastatin Drug: Comparator: atorvastatin Drug: Comparator: rosuvastatin

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations

Patients with diabetes, cardiovascular disease (CVD) or a “high risk” of developing CVD and a fasting LDL-C level of ≥2mmol/l, having been on simvastatin 40mg for 6 weeks were assigned to 10/40 mg ezetimibe/simvastatin; 40 mg atorvastatin; 10 mg rosuvastatin (5 mg in elderly/Asian patients (in line with UK SPC)) between 27/03/2007 and 31/03/2008

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment

All patients were subjected to a 6 week run-in period on open label 40 mg simvastatin to stabilise their LDL-C levels. Patients whose LDL-C at the end of this period was below 2.0 mmol/l or who were <75% compliant with run-in medication, were excluded from the study

Reporting Groups

	Description
Ezetimibe/Simvastatin	ezetimibe (+) simvastatin 10/40mg. once daily tablet formulation, all tablet form, taken orally
Atorvostatin	atorvastatin 40mg. once daily tablet formulation, all tablet form, taken orally
Rosuvastatin	rosuvastatin 10 mg. once daily tablet formulation, all tablet form, taken orally

Participant Flow: Overall Study

	Ezetimibe/Simvastatin	Atorvostatin	Rosuvastatin
STARTED	**261**	**263**	**262**
COMPLETED	**249**	**252**	**251**
NOT COMPLETED	**12**	**11**	**11**
Adverse Event	**7**	**5**	**9**
Protocol Violation	**0**	**2**	**1**
Withdrew consent	**3**	**3**	**0**
Lost to Follow-up	**1**	**1**	**1**
Discontinued after 41 days Rx	**1**	**0**	**0**

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.

No text entered.

Reporting Groups

	Description
Ezetimibe/Simvastatin	ezetimibe (+) simvastatin 10/40mg. once daily tablet formulation, all tablet form, taken orally
Atorvostatin	atorvastatin 40mg. once daily tablet formulation, all tablet form, taken orally
Rosuvastatin	rosuvastatin 10 mg. once daily tablet formulation, all tablet form, taken orally
Total	Total of all reporting groups

Baseline Measures

	Ezetimibe/Simvastatin	Atorvostatin	Rosuvastatin	Total
Number of Participants [units: participants]	**261**	**263**	**262**	**786**

Age [units: years] Mean (Standard Deviation)	**64.7 (8.65)**	**64.2 (8.44)**	**63.9 (8.61)**	**64.3 (8.56)**
Age, Customized [units: participants]				
< 70 years	**185**	**187**	**195**	**567**
>=70 years	**76**	**76**	**67**	**219**
Gender [units: participants]				
Female	**101**	**78**	**84**	**263**
Male	**160**	**185**	**178**	**523**
Race/Ethnicity, Customized [units: Participants]				
Asian	**3**	**0**	**2**	**5**
White	**254**	**261**	**257**	**772**
Black	**4**	**0**	**2**	**6**
Other	**0**	**2**	**1**	**3**

Outcome Measures

1. Primary: Percentage of Patients Achieving a Target of Fasting LDL-C of <2mmol/l at Study End [Time Frame: 6 Weeks]

Show Outcome Measure 1

Serious Adverse Events

Show Serious Adverse Events

Other Adverse Events

Show Other Adverse Events

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data
No text entered.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.
There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial

results after the trial is completed.

The agreement is:

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☑ Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.

Restriction Description: Merck agreements may vary with individual investigators, but will not prohibit any investigator from publishing. Merck supports the publication of results from all centers of a multi-center trial but requests that reports based on single-site data not precede the primary publication of the entire clinical trial.

Results Point of Contact:

Name/Title: Senior Vice President, Global Clinical Development
Organization: Merck Sharp & Dohme Corp
phone: 1-800-672-6372

Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

McCormack T, Harvey P, Gaunt R, Allgar V, Chipperfield R, Robinson P; IN-PRACTICE study. Incremental cholesterol reduction with ezetimibe/simvastatin, atorvastatin and rosuvastatin in UK General Practice (IN-PRACTICE): randomised controlled trial of achievement of Joint British Societies (JBS-2) cholesterol targets. Int J Clin Pract. 2010 Jul;64(8):1052-61. doi: 10.1111/j.1742-1241.2010.02429.x. Epub 2010 May 12.

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