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Search

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Find Studies | About Clinical Studies | Submit Studies | Resources | About This Site

Home > Find Studies > Search Results > Study Record Detail
Text Size

Trial record **1 of 1** for: NCT00423579
Previous Study | Return to List | Next Study

The Effects of Ezetimibe/Simvastatin 10/20 mg Versus Simvastatin 40 mg in High Cholesterol and Coronary Heart Disease Study (P04039AM2)(COMPLETED)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

Collaborator:
Schering-Plough

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

ClinicalTrials.gov Identifier:
NCT00423579

First received: January 17, 2007
Last updated: April 1, 2015
Last verified: April 2015
History of Changes

Full Text View | Tabular View | Study Results | Disclaimer | How to Read a Study Record

Purpose

This study is being conducted to compare the efficacy, safety, and tolerability of ezetimibe/simvastatin 10/20 mg when administered daily versus doubling the dose of simvastatin to 40 mg in patients with hypercholesterolemia and coronary heart disease.

Condition	Intervention	Phase
Hypercholesterolemia Coronary Disease	Drug: Ezetimibe/Simvastatin 10/20 mg Drug: simvastatin 40 mg	Phase 4

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

Official Title: A Multicenter, Randomized, Parallel-Groups, Double-Blind Placebo-Controlled Study Comparing the Efficacy, Safety, and Tolerability of Administration of Ezetimibe/Simvastatin Tablet 10/20 mg Versus Doubling the Dose of Simvastatin 20 mg [Simvastatin 40 mg] in Subjects With Primary Hypercholesterolemia and Coronary Heart Disease

Resource links provided by NLM:

MedlinePlus related topics: Cholesterol Coronary Artery Disease Heart Diseases

Drug Information available for: Simvastatin Ezetimibe

U.S. FDA Resources

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

Primary Outcome Measures:

- Change in Low-density-lipoprotein Cholesterol (LDL-C) at 6 Weeks [Time Frame: Baseline and 6 weeks] [Designated as safety issue: No]

  Percentage change in LDL C from baseline to endpoint after 6 weeks of treatment.

Enrollment:	120
Study Start Date:	July 2006
Study Completion Date:	March 2008
Primary Completion Date:	March 2008 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Ezetimibe/Simvastatin 10/20 mg + Simvastatin placebo Subjects will receive 2 tablets. The first tablet is Ezetimibe/Simvastatin 10/20 mg. The second tablet is simvastatin placebo. Subjects will receive a maximum of 6 weeks of treatment	Drug: Ezetimibe/Simvastatin 10/20 mg 1 tablet containing 10 mg of ezetimibe and 20 mg of simvastatin per day for 6 weeks
Active Comparator: Ezetimibe/Simvastatin placebo + Simvastatin 40 mg Subjects will receive 2 tablets. The first tablet is Ezetimibe/Simvastatin placebo. The second tablet is simvastatin 40 mg. Subjects will receive a maximum of 6 weeks of treatment.	Drug: simvastatin 40 mg 1 tablet containing 40 mg of simvastatin per day for 6 weeks

Eligibility

Ages Eligible for Study:	18 Years to 75 Years
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Subjects must have documented coronary heart disease (CHD). For the purposes of this study, CHD will include one or more of the following features: documented stable angina (with evidence of ischemia on exercise testing); history of myocardial infarction; history of percutaneous coronary intervention [PCI] (primarily PCI with or without stent placement); symptomatic peripheral vascular disease (claudication); documented history of atherothrombotic cerebrovascular disease; and/or documented history of unstable angina or non-Q wave myocardial infarction.
- Subjects must demonstrate their willingness to participate in the study and comply with its procedures by signing a written informed consent.
- History of myocardial infarction (heart attack).
- Subjects must be >= 18 years and <= 75 years of age.
- Subjects must have an LDL-C concentration >= 2.6 mmol/L (100 mg/dL) to <= 4.1 mmol/L (160 mg/dL) at the time of randomization (Visit 3/Baseline Visit).
- Subjects must have triglyceride concentrations of < 3.99 mmol/L (350 mg/dL) at (Visit 3 Baseline Visit).
- Subject must be currently taking simvastatin 20 mg daily.
- Subjects must have liver transaminases (ALT [alanine aminotransferase], AST [aspartate aminotransferase]) < 50% above the upper limit of normal, with no active liver disease, and CK (creatine kinase) < 50% above the upper limit of normal at Visit 3 (Baseline Visit).
- Clinical laboratory tests (complete blood count [CBC], blood chemistries, urinalysis) must be within normal limits or clinically acceptable to the investigator at Visit 3 (Baseline Visit).
- Subjects must have maintained a cholesterol-lowering diet and exercise program for at least 4 weeks prior to the study and be willing to continue the same diet and exercise program during the study.
- Subjects must report a stable weight history for at least 4 weeks prior to entry into study at Visit 3 (Baseline Visit).
- Women receiving hormonal therapy, including hormone replacement, any estrogen antagonist/agonist, or oral contraceptives, must have been maintained on a stable dose and regimen for at least 8 weeks and be willing to continue the same regimen for the duration of the study.
- Women of childbearing potential (includes women who are less than 1 year postmenopausal and women who become sexually active) must be using an acceptable method of birth control (e.g., hormonal contraceptive, medically prescribed intrauterine device [IUD], condom in combination with spermicide) or be surgically sterilized (e.g., hysterectomy or tubal ligation).
- Subjects must be free of any clinically significant diseases other than hyperlipidemia or coronary heart disease that would interfere with study evaluations.

- Subjects must understand and be able to adhere to the dosing and visit schedules, and must agree to remain on their cholesterol-lowering diet and their exercise regimen for the duration of the study.

Exclusion Criteria:

- Subjects whose body mass index (BMI = weight [kg]/height2 [m]) is >= 35 kg/m^2 at Visit 3 (Baseline Visit).
- Subjects who consume > 14 alcoholic drinks per week. (A drink is: a can of beer, glass of wine, or single measure of spirits).
- Any condition or situation which, in the opinion of the investigator, might pose a risk to the subject or interfere with participation in the study.
- Women who are pregnant or nursing.

Exclusion Criteria: subjects who have the following medical conditions:

- Congestive heart failure defined by New York Heart Association (NYHA) as Class III or IV.
- Uncontrolled cardiac arrhythmia.
- Myocardial infarction, acute coronary insufficiency, coronary artery bypass surgery, or angioplasty within 3 months of Visit 3 (Baseline Visit).
- Unstable or severe peripheral artery disease within 3 months of Visit 3 (Baseline Visit).
- Newly diagnosed or currently unstable angina pectoris (chest pain).
- Uncontrolled hypertension (treated or untreated) with systolic blood pressure > 160 mm Hg or diastolic > 100 mm Hg at Visit 3 (Baseline Visit).
- Type I or Type II diabetes mellitus.
- Uncontrolled endocrine or metabolic disease known to influence serum lipids or lipoproteins, i.e., secondary causes of hyperlipidemia, such as secondary hypercholesterolemia due to hypothyroidism (thyroid stimulating hormone [TSH] above upper limit of normal) at Visit 3. Subjects with a history of hypothyroidism who are on a stable therapy of thyroid hormone replacement for at least 6 weeks are eligible for enrollment if TSH levels are within normal limits at Visit 3 (Baseline Visit).
- Impaired renal function (creatinine > 2.0 mg/dL) or nephrotic syndrome at Visit 3 (Baseline Visit).
- Disorders of the hematologic, digestive, or central nervous systems including cerebrovascular disease and degenerative disease that would limit study evaluation or participation.
- Known Human Immunodeficiency Virus (HIV) positive.
- Cancer within the past 5 years (except for successfully treated basal and squamous cell carcinomas).
- History of mental instability, drug/alcohol abuse within the past 5 years, or major psychiatric illness not adequately controlled and stable on pharmacotherapy.

Exclusion Criteria: subjects who are on any of the following concomitant medications:

- Subjects who have not observed the designated wash-out period for any of the prohibited medications.
- Subjects who have not stopped taking various prohibited medications for a minimum period of time before Visit 3, including amiodarone hydrochloride (6 months) and probucol (12 months).
- Subjects currently consuming large amounts of grapefruit juice (> 1 liter/day).
- Oral corticosteroids, unless used as replacement therapy for pituitary/adrenal disease and the subject is on a stable regimen for at least 6 weeks prior to Visit 3 (Baseline Visit).
- Subjects who are currently using cardiovascular medication (e.g. antihypertensive, antiarrhythmic) and have not been on a stable regimen for at least 6 weeks prior to Visit 3 (Baseline Visit) and it is expected to change during the study.
- Subjects who are currently using psyllium, other fiber-based laxatives, and/or any other over-the-counter (OTC) therapy known to affect serum lipid levels (phytosterol margarine), and have not been on a stable regimen for at least 5 weeks prior to study entry Visit 3 (Baseline Visit) and who do not agree to remain on this regimen throughout the study.
- Subject who are currently using orlistat or sibutramine.
- Subjects who are currently using amiodarone hydrochloride.
- Subjects who are currently using danazol.
- Subjects who are currently using coumarin anticoagulants (warfarin).
- Subjects who are using (at the Screening Visit / Visit 1) any statin other than simvastatin 20 mg, or ezetimibe alone or in combination with any statin (including the fixed combination with simvastatin).

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.

No Contacts or Locations Provided

More Information

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

Averna M, Zaninelli A, Le Grazie C, Gensini GF. Ezetimibe/simvastatin 10/20 mg versus simvastatin 40 mg in coronary heart disease patients. J Clin Lipidol. 2010 Jul-Aug;4(4):272-8. doi: 10.1016/j.jacl.2010.05.002. Epub 2010 Jun 1.

Rotella CM, Zaninelli A, Le Grazie C, Hanson ME, Gensini GF. Ezetimibe/simvastatin vs simvastatin in coronary heart disease patients with or without diabetes. Lipids Health Dis. 2010 Jul 27;9:80. doi: 10.1186/1476-511X-9-80.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00423579 History of Changes
Other Study ID Numbers:	P04039
Study First Received:	January 17, 2007
Results First Received:	March 19, 2009
Last Updated:	April 1, 2015
Health Authority:	Italy: Ministry of Health

Additional relevant MeSH terms:

Coronary Artery Disease	Vascular Diseases
Coronary Disease	Ezetimibe
Heart Diseases	Simvastatin
Hypercholesterolemia	Anticholesteremic Agents
Myocardial Ischemia	Antimetabolites
Arterial Occlusive Diseases	Enzyme Inhibitors
Arteriosclerosis	Hydroxymethylglutaryl-CoA Reductase Inhibitors
Cardiovascular Diseases	Hypolipidemic Agents
Dyslipidemias	Lipid Regulating Agents
Hyperlipidemias	Molecular Mechanisms of Pharmacological Action
Lipid Metabolism Disorders	Pharmacologic Actions
Metabolic Diseases	Therapeutic Uses

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TO TOP

For Patients and Families | For Researchers | For Study Record Managers

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Home > Find Studies > Search Results > Study Record Detail
Text Size

Trial record **1 of 1** for: NCT00423579
Previous Study | Return to List | Next Study

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Results First Received: March 19, 2009

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor); Primary Purpose: Treatment
Conditions:	Hypercholesterolemia Coronary Disease
Interventions:	Drug: Ezetimibe/Simvastatin 10/20 mg Drug: simvastatin 40 mg

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
No text entered.

Pre-Assignment Details

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

Visits 1 and 2 were for screening, combined if wash-out not required. One ineligible subject mistakenly received assignment at Visit 2 and was removed. The subject did not receive treatment. Actual enrollment: 120 subjects. Intent-to-treat (ITT) population included only evaluable subjects; as such analysis based on 112 subjects.

Reporting Groups

	Description
Ezetimibe/Simvastatin 10/20 mg + Simvastatin Placebo	Subjects in the Intent-to-Treat Population. Subjects will receive 2 tablets. The first tablet is Ezetimibe/Simvastatin 10/20 mg. The second tablet is simvastatin placebo. Subjects will receive a maximum of 6 weeks of treatment
Ezetimibe/Simvastatin Placebo + Simvastatin 40 mg	Subjects in the Intent-to-Treat population. Subjects will receive 2 tablets. The first tablet is Ezetimibe/Simvastatin placebo. The second tablet is simvastatin 40 mg. Subjects will receive a maximum of 6 weeks of treatment.

Participant Flow: Overall Study

	Ezetimibe/Simvastatin 10/20 mg + Simvastatin Placebo	Ezetimibe/Simvastatin Placebo + Simvastatin 40 mg
STARTED	**60** [1]	**60**
COMPLETED	**56** [2]	**56** [2]
NOT COMPLETED	**4**	**4**
Lost to Follow-up	**3**	**0**
Protocol Violation	**1**	**3**
Diagnosis of diabetes	**0**	**1**

[1] 61 enrolled, however one subject was ineligible and was removed.
[2] These 56 subjects were the Intent-to-Treat population. Analysis based on ITT population.

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 10/20 mg + Simvastatin Placebo	Subjects in the Intent-to-Treat Population. Subjects will receive 2 tablets. The first tablet is Ezetimibe/Simvastatin 10/20 mg. The second tablet is simvastatin placebo. Subjects will receive a maximum of 6 weeks of treatment
Ezetimibe/Simvastatin Placebo + Simvastatin 40 mg	Subjects in the Intent-to-Treat population. Subjects will receive 2 tablets. The first tablet is Ezetimibe/Simvastatin placebo. The second tablet is simvastatin 40 mg. Subjects will receive a maximum of 6 weeks of treatment.
Total	Total of all reporting groups

Baseline Measures

	Ezetimibe/Simvastatin 10/20 mg + Simvastatin Placebo	Ezetimibe/Simvastatin Placebo + Simvastatin 40 mg	Total

Number of Participants [units: participants]	**56**	**56**	**112**
Age [1] [units: years] Mean (Standard Deviation)	**61.3 (8.4)**	**62.1 (7.8)**	**61.7 (8.1)**
Gender [2] [units: participants]			
Female	**26**	**24**	**50**
Male	**30**	**32**	**62**

[1] Mean age based on Intent-to-Treat population.
[2] Gender totals based on Intent-to-Treat population.

Outcome Measures

1. Primary: Change in Low-density-lipoprotein Cholesterol (LDL-C) at 6 Weeks [Time Frame: Baseline and 6 weeks]

Hide Outcome Measure 1

Measure Type	Primary
Measure Title	Change in Low-density-lipoprotein Cholesterol (LDL-C) at 6 Weeks
Measure Description	Percentage change in LDL C from baseline to endpoint after 6 weeks of treatment.
Time Frame	Baseline and 6 weeks
Safety Issue	No

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.
Intent-to-treat population only.

Reporting Groups

	Description
Ezetimibe/Simvastatin 10/20 mg + Simvastatin Placebo	Subjects in the Intent-to-Treat Population. Subjects will receive 2 tablets. The first tablet is Ezetimibe/Simvastatin 10/20 mg. The second tablet is simvastatin placebo. Subjects will receive a maximum of 6 weeks of treatment
Ezetimibe/Simvastatin Placebo + Simvastatin 40 mg	Subjects in the Intent-to-Treat population. Subjects will receive 2 tablets. The first tablet is Ezetimibe/Simvastatin placebo. The second tablet is simvastatin 40 mg. Subjects will receive a maximum of 6 weeks of treatment.

Measured Values

	Ezetimibe/Simvastatin 10/20 mg + Simvastatin Placebo	**Ezetimibe/Simvastatin Placebo + Simvastatin 40 mg**
Number of Participants Analyzed [units: participants]	**56**	**56**
Change in Low-density-lipoprotein Cholesterol		

(LDL-C) at 6 Weeks [units: percentage change] Mean (Standard Deviation)	**-26.5 (9.5)**	**-11.9 (13.6)**

Statistical Analysis 1 for Change in Low-density-lipoprotein Cholesterol (LDL-C) at 6 Weeks

Groups [1]	All groups
Method [2]	Student's t test for independent data
P Value [3]	0.0000
Mean Difference (Net) [4]	-14.5
95% Confidence Interval	-18.9 to -10.1

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	Difference in percentage change in mean LDL-C values (change from baseline to week 6) between the two treatment groups. (Ezetimibe [EZ]/Simvastatin [S] [10/20mg] + S [placebo] group minus the EZ/S [10mg/placebo] + S [40mg] group)

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Reporting Groups

	Description
Ezetimibe/Simvastatin 10/20 mg + Simvastatin Placebo	Subjects in the Intent-to-Treat Population. Subjects will receive 2 tablets. The first tablet is Ezetimibe/Simvastatin 10/20 mg. The second tablet is simvastatin placebo. Subjects will receive a maximum of 6 weeks of treatment
Ezetimibe/Simvastatin Placebo + Simvastatin 40 mg	Subjects in the Intent-to-Treat population. Subjects will receive 2 tablets. The first tablet is Ezetimibe/Simvastatin placebo. The second tablet is simvastatin 40 mg. Subjects will receive a maximum of 6 weeks of treatment.

Serious Adverse Events

	Ezetimibe/Simvastatin 10/20 mg + Simvastatin Placebo	**Ezetimibe/Simvastatin Placebo + Simvastatin 40 mg**

Total, serious adverse events		
# participants affected / at risk	**0/60 (0.00%)**	**1/60 (1.67%)**
Cardiac disorders		
Transient Ischemic Attack †		
# participants affected / at risk	**0/60 (0.00%)**	**1/60 (1.67%)**
# events	**0**	**1**

† Events were collected by systematic assessment

Other Adverse Events

Hide Other Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Ezetimibe/Simvastatin 10/20 mg + Simvastatin Placebo	Subjects in the Intent-to-Treat Population. Subjects will receive 2 tablets. The first tablet is Ezetimibe/Simvastatin 10/20 mg. The second tablet is simvastatin placebo. Subjects will receive a maximum of 6 weeks of treatment
Ezetimibe/Simvastatin Placebo + Simvastatin 40 mg	Subjects in the Intent-to-Treat population. Subjects will receive 2 tablets. The first tablet is Ezetimibe/Simvastatin placebo. The second tablet is simvastatin 40 mg. Subjects will receive a maximum of 6 weeks of treatment.

Other Adverse Events

	Ezetimibe/Simvastatin 10/20 mg + Simvastatin Placebo	**Ezetimibe/Simvastatin Placebo + Simvastatin 40 mg**
Total, other (not including serious) adverse events		
# participants affected / at risk	**0/60 (0.00%)**	**0/60 (0.00%)**

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:** The investigator shall not publish or publicly present the study results without prior written authorization from the sponsor, except for dispositions in the Ministerial Circular n. 6 dated 02 SEP 2002. The investigator shall notify the sponsor in writing of any publication submission or presentation reporting results of the study 30 days prior to submission or presentation to permit sponsor review.

Results Point of Contact:

Name/Title: Senior Vice President, Global Clinical Development
Organization: Merck Sharp & Dohme Corp.
e-mail: ClinicalTrialsDisclosure@merck.com

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

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Health Authority:	Italy: Ministry of Health

TO TOP

For Patients and Families | For Researchers | For Study Record Managers

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