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

Trial record **1 of 1** for: NCT00617123
Previous Study | Return to List | Next Study

Trial to Assess the Ocular Safety of Vorapaxar (SCH 530348) in Participants With Atherosclerosis (Study P05183)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

Collaborators:
The TIMI (Thrombolysis in Myocardial Infarction) Study Group
Duke Clinical Research Institute

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

ClinicalTrials.gov Identifier:
NCT00617123

First received: February 4, 2008
Last updated: January 14, 2015
Last verified: January 2015
History of Changes

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

Purpose

This study is designed to evaluate the long-term ocular safety of SCH 530348 (vorapaxar) in participants with established atherosclerotic disease who are enrolled into the TRA 2°P - TIMI 50 Study (P04737) (NCT00526474).

Condition	Intervention	Phase
Atherosclerosis Ischemia Myocardial Infarction Cerebrovascular Accident	Drug: Vorapaxar 2.5 mg Drug: Placebo	Phase 3

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

Official Title: A Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Ocular Safety of SCH 530348 in Subjects Participating in the Schering-Plough P04737 Study (TRA^SM-Secondary Prevention Ocular Safety Study)

Resource links provided by NLM:

MedlinePlus related topics: Atherosclerosis

Drug Information available for: Vorapaxar Vorapaxar sulfate

U.S. FDA Resources

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

Primary Outcome Measures:

- Number of Participants Who Develop Vacuolization in the Inner Nuclear Layer (INL) of the Retina as Measured by Ocular Coherence Tomography (OCT) [Time Frame: Up to 12 months] [Designated as safety issue: Yes]

  Vacuolization is defined as the presence of more than one vacuole (defined as a clear, round structure in the INL of the retina of at least 30 microns in diameter) compared to baseline in either the left or right eye as evaluated by ocular coherence tomography (OCT).

Secondary Outcome Measures:

- Number of Participants Who Have a Decrease in Visual Acuity Score of at Least Seven Letters From Baseline [Time Frame: Baseline and 4, 8 and 12 months] [Designated as safety issue: Yes]

  Visual acuity was assessed in both eyes by best corrected visual acuity following standardized refraction. The best corrected visual acuity score is the number of letters on a standard visual acuity testing chart read correctly by a participant. A decrease in best corrected visual acuity score in the left and/or right eye indicates a worsening of vision.

- Number of Participants With Change From Baseline of Center Foveal Thickness of Greater Than 15 Microns as Measured by OCT [Time Frame: Baseline and 4, 8 and 12 months] [Designated as safety issue: Yes]

  Center foveal thickness measured by OCT was evaluated for a change from baseline in greater than 15 microns in either the left or right eye.

- Change From Baseline in the Numerical Score of Graded Abnormalities as Measured by OCT [Time Frame: Baseline and 4, 8 and 12 months] [Designated as safety issue: Yes]

  Individual OCT abnormalities were scored as 0=not present or 1=present. The total number of possible abnormalities present was 84 (42 possible abnormalities per eye). Data are for the left and right eyes combined (score range: 0 to 84). Change from Baseline at a given timepoint was calculated as Timepoint Score minus Baseline Score. A smaller score indicates fewer graded abnormalities.

- Change From Baseline in the Numerical Score of Graded Abnormalities as Measured by Fundus Photography [Time Frame: Baseline and 4, 8 and 12 months] [Designated as safety issue: Yes]

  Individual fundus photography abnormalities were scored as 0=not present or 1=present. The total number of possible abnormalities present was 48 (24 possible abnomalities per eye). Data are for the left and right eyes combined (score range: 0 to 48). Change from Baseline at a given timepoint was calculated as Timepoint Score minus Baseline Score. A smaller score indicates fewer graded abnormalities.

Enrollment:	258
Study Start Date:	July 2008
Study Completion Date:	October 2010
Primary Completion Date:	October 2010 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Vorapaxar Participants receive a vorapaxar 2.5 mg tablet administered orally once daily for 1 year	Drug: Vorapaxar 2.5 mg Vorapaxar 2.5 mg oral tablet
Placebo Comparator: Placebo Participants receive a matching placebo tablet to vorapaxar administered orally once daily for 1 year	Drug: Placebo matching placebo oral tablet

Eligibility

Ages Eligible for Study:	18 Years and older
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Evidence or a history of atherosclerosis involving the coronary, cerebral, or peripheral vascular systems

Exclusion Criteria:

- The study will include participants who meet none of the exclusion criteria for the parent protocol (P04737) and also the following:
  - history or evidence of age-related macular degeneration on baseline evaluation
  - history of diabetic macular edema, or evidence of treated diabetic retinopathy on baseline evaluation
  - history or evidence of other retinal diseases, including retinal injury, on baseline evaluation
  - history or evidence of retinal surgery, including laser photocoagulation, on baseline evaluation
  - history or evidence of glaucoma on baseline evaluation
  - history or evidence of high intraocular pressure of >22 mm Hg on baseline evaluation
  - evidence of center foveal thickness of >190 µm on baseline OCT examination
  - presence of vacuoles in the retina on baseline OCT

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

No publications provided

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00617123 History of Changes
Other Study ID Numbers:	P05183, MK-5348-018
Study First Received:	February 4, 2008
Results First Received:	May 9, 2014
Last Updated:	January 14, 2015
Health Authority:	United States: Food and Drug Administration

Additional relevant MeSH terms:

Arteriosclerosis	Brain Ischemia
Atherosclerosis	Cardiovascular Diseases
Cerebral Infarction	Central Nervous System Diseases
Myocardial Infarction	Cerebrovascular Disorders
Stroke	Heart Diseases
Arterial Occlusive Diseases	Myocardial Ischemia
Brain Diseases	Nervous System Diseases
Brain Infarction	Vascular Diseases

ClinicalTrials.gov processed this record on July 13, 2015

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

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Previous Study | Return to List | Next Study

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Results First Received: May 9, 2014

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator, Outcomes Assessor); Primary Purpose: Prevention
Conditions:	Atherosclerosis Ischemia Myocardial Infarction Cerebrovascular Accident
Interventions:	Drug: Vorapaxar 2.5 mg Drug: Placebo

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

Participants were recruited from participants enrolled in Study SCH 530348 P04737 (NCT00526474) and met the inclusion/exclusion criteria for this study.

Pre-Assignment Details

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

A total of 258 particpants were referred to opthalmology sites, 65 of whom did not particpate in this study (P05138) beyond the screening visit and were not included in the analysis of ocular safety. A total of 193 participants were included in the analysis of ocular safety.

Reporting Groups

	Description
Vorapaxar	Participants receive a vorapaxar 2.5 mg tablet administered orally once daily for 1 year
Placebo	Participants receive a matching placebo tablet to vorapaxar administered orally once daily for 1 year

Participant Flow for 2 periods

Period 1: Referral Screening Period

	Vorapaxar	Placebo
STARTED	**137**	**121**
COMPLETED	**98**	**95**
NOT COMPLETED	**39**	**26**
Did Not Meet Protocol Eligibility	**36**	**24**
Did Not Wish To Continue	**3**	**1**
Adverse Event	**0**	**1**

Period 2: Study Treatment Period

	Vorapaxar	Placebo
STARTED	**98**	**95**
Treated	**97** [1]	**95**
COMPLETED	**81**	**79**
NOT COMPLETED	**17**	**16**
Withdrawal by Subject	**8**	**12**
Adverse Event	**7**	**3**
Did Not Meet Protocol Eligibility	**2**	**0**
Noncompliance with Protocol	**0**	**1**

[1] 1 participant was not treated

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.

Participants who were included in the analysis of ocular safety.

Reporting Groups

	Description
Vorapaxar	Participants receive a vorapaxar 2.5 mg tablet administered orally once daily for 1 year

Placebo	Participants receive a matching placebo tablet to vorapaxar administered orally once daily for 1 year
Total	Total of all reporting groups

Baseline Measures

	Vorapaxar	Placebo	Total
Number of Participants [units: participants]	**98**	**95**	**193**
Age [units: years] Mean (Standard Deviation)	**56.6 (10.1)**	**55.3 (11.7)**	**55.9 (10.9)**
Gender [units: participants]			
Female	**27**	**26**	**53**
Male	**71**	**69**	**140**

Outcome Measures

Hide All Outcome Measures

1. Primary: Number of Participants Who Develop Vacuolization in the Inner Nuclear Layer (INL) of the Retina as Measured by Ocular Coherence Tomography (OCT) [Time Frame: Up to 12 months]

Measure Type	Primary
Measure Title	Number of Participants Who Develop Vacuolization in the Inner Nuclear Layer (INL) of the Retina as Measured by Ocular Coherence Tomography (OCT)
Measure Description	Vacuolization is defined as the presence of more than one vacuole (defined as a clear, round structure in the INL of the retina of at least 30 microns in diameter) compared to baseline in either the left or right eye as evaluated by ocular coherence tomography (OCT).
Time Frame	Up to 12 months
Safety Issue	Yes

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.
The analysis population consisted of all participants who took at least one dose of study medication, and had a baseline and at least one post-baseline vacuolation assessment.

Reporting Groups

	Description
Vorapaxar	Participants receive a vorapaxar 2.5 mg tablet administered orally once daily for 1 year
Placebo	Participants receive a matching placebo tablet to vorapaxar administered orally once daily for 1 year

Measured Values

	Vorapaxar	Placebo

Number of Participants Analyzed [units: participants]	**91**	**86**
Number of Participants Who Develop Vacuolization in the Inner Nuclear Layer (INL) of the Retina as Measured by Ocular Coherence Tomography (OCT) [units: participants]		
4 months (n=91, n=86)	**1**	**0**
8 months (n=86, n=80)	**1**	**0**
12 months (n=77, n=78)	**0**	**0**

No statistical analysis provided for Number of Participants Who Develop Vacuolization in the Inner Nuclear Layer (INL) of the Retina as Measured by Ocular Coherence Tomography (OCT)

2. Secondary: Number of Participants Who Have a Decrease in Visual Acuity Score of at Least Seven Letters From Baseline [Time Frame: Baseline and 4, 8 and 12 months]

Measure Type	Secondary
Measure Title	Number of Participants Who Have a Decrease in Visual Acuity Score of at Least Seven Letters From Baseline
Measure Description	Visual acuity was assessed in both eyes by best corrected visual acuity following standardized refraction. The best corrected visual acuity score is the number of letters on a standard visual acuity testing chart read correctly by a participant. A decrease in best corrected visual acuity score in the left and/or right eye indicates a worsening of vision.
Time Frame	Baseline and 4, 8 and 12 months
Safety Issue	Yes

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.
The analysis population consisted of all participants who took at least one dose of study medication, and had a baseline and at least one post-baseline visual acuity score.

Reporting Groups

	Description
Vorapaxar	Participants receive a vorapaxar 2.5 mg tablet administered orally once daily for 1 year
Placebo	Participants receive a matching placebo tablet to vorapaxar administered orally once daily for 1 year

Measured Values

	Vorapaxar	**Placebo**
Number of Participants Analyzed [units: participants]	**90**	**86**
Number of Participants Who Have a Decrease in Visual Acuity Score of at Least Seven Letters From Baseline [units: participants]		
4 months (n=90, n=86)	**10**	**8**
8 months (n=86, n=80)	**10**	**8**
12 months (n=78, n=78)	**7**	**9**

No statistical analysis provided for Number of Participants Who Have a Decrease in Visual Acuity Score of at Least Seven Letters From Baseline

3. Secondary: Number of Participants With Change From Baseline of Center Foveal Thickness of Greater Than 15 Microns as Measured by OCT [Time Frame: Baseline and 4, 8 and 12 months]

Measure Type	Secondary
Measure Title	Number of Participants With Change From Baseline of Center Foveal Thickness of Greater Than 15 Microns as Measured by OCT
Measure Description	Center foveal thickness measured by OCT was evaluated for a change from baseline in greater than 15 microns in either the left or right eye.
Time Frame	Baseline and 4, 8 and 12 months
Safety Issue	Yes

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.
The analysis population consisted of all participants who took at least one dose of study medication, and had a baseline and at least one post-baseline center point thickness assessment by OCT.

Reporting Groups

	Description
Vorapaxar	Participants receive a vorapaxar 2.5 mg tablet administered orally once daily for 1 year
Placebo	Participants receive a matching placebo tablet to vorapaxar administered orally once daily for 1 year

Measured Values

	Vorapaxar	**Placebo**
Number of Participants Analyzed [units: participants]	**91**	**86**
Number of Participants With Change From Baseline of Center Foveal Thickness of Greater Than 15 Microns as Measured by OCT [units: participants]		
4 months (n=91, n=86)	**27**	**28**
8 months (n=86, n=80)	**23**	**26**
12 months (n=77, n=78)	**19**	**29**

No statistical analysis provided for Number of Participants With Change From Baseline of Center Foveal Thickness of Greater Than 15 Microns as Measured by OCT

4. Secondary: Change From Baseline in the Numerical Score of Graded Abnormalities as Measured by OCT [Time Frame: Baseline and 4, 8 and 12 months]

Measure Type	Secondary
Measure Title	Change From Baseline in the Numerical Score of Graded Abnormalities as Measured by OCT

Measure Description	Individual OCT abnormalities were scored as 0=not present or 1=present. The total number of possible abnormalities present was 84 (42 possible abnormalities per eye). Data are for the left and right eyes combined (score range: 0 to 84). Change from Baseline at a given timepoint was calculated as Timepoint Score minus Baseline Score. A smaller score indicates fewer graded abnormalities.
Time Frame	Baseline and 4, 8 and 12 months
Safety Issue	Yes

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.
The analysis population consisted of all participants who took at least one dose of study medication, and had a baseline and at least one post-baseline numerical score of graded abnormalities assessment by OCT.

Reporting Groups

	Description
Vorapaxar	Participants receive a vorapaxar 2.5 mg tablet administered orally once daily for 1 year
Placebo	Participants receive a matching placebo tablet to vorapaxar administered orally once daily for 1 year

Measured Values

	Vorapaxar	**Placebo**
Number of Participants Analyzed [units: participants]	**92**	**87**
Change From Baseline in the Numerical Score of Graded Abnormalities as Measured by OCT [units: score on a scale] Mean (Standard Error)		
Baseline score (n=92, n=87)	**3.1 (0.3)**	**3.4 (0.4)**
4 months change (n=91, n=86)	**0.2 (0.3)**	**0.7 (0.3)**
8 months change (n=86, n=80)	**0.6 (0.3)**	**0.9 (0.3)**
12 months change (n=77, n=78)	**0.2 (0.3)**	**0.0 (0.3)**

No statistical analysis provided for Change From Baseline in the Numerical Score of Graded Abnormalities as Measured by OCT

5. Secondary: Change From Baseline in the Numerical Score of Graded Abnormalities as Measured by Fundus Photography [Time Frame: Baseline and 4, 8 and 12 months]

Measure Type	Secondary
Measure Title	Change From Baseline in the Numerical Score of Graded Abnormalities as Measured by Fundus Photography
Measure Description	Individual fundus photography abnormalities were scored as 0=not present or 1=present. The total number of possible abnormalities present was 48 (24 possible abnomalities per eye). Data are for the left and right eyes combined (score range: 0 to 48). Change from Baseline at a given timepoint was calculated as Timepoint Score minus Baseline Score. A smaller score indicates fewer graded abnormalities.
Time Frame	Baseline and 4, 8 and 12 months
Safety Issue	Yes

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.

The analysis population consisted of all participants who took at least one dose of study medication, and had a baseline and at least one post-baseline numerical score of graded abnormalities assessment as measured by fundus photogrpahy.

Reporting Groups

	Description
Vorapaxar	Participants receive a vorapaxar 2.5 mg tablet administered orally once daily for 1 year
Placebo	Participants receive a matching placebo tablet to vorapaxar administered orally once daily for 1 year

Measured Values

	Vorapaxar	Placebo
Number of Participants Analyzed [units: participants]	**91**	**87**
Change From Baseline in the Numerical Score of Graded Abnormalities as Measured by Fundus Photography [units: score on a scale] Mean (Standard Error)		
Baseline score (n=91, n=87)	**4.1 (0.4)**	**3.9 (0.4)**
4 months change (n=90, n=86)	**-0.2 (0.4)**	**-0.4 (0.3)**
8 months change (n=86, n=80)	**-0.4 (0.4)**	**-0.6 (0.4)**
12 months change (n=76, n=77)	**-0.6 (0.5)**	**-0.3 (0.5)**

No statistical analysis provided for Change From Baseline in the Numerical Score of Graded Abnormalities as Measured by Fundus Photography

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	Participant safety data collected on the eCRF for this study (SCH 530348 P05183) were limited to ocular test results. These ocular test results were not captured as adverse events, but were captured as part of outcome measures. All other participant adverse events were collected under the Study SCH 530348 P04737 (NCT00526474) parent protocol.

Reporting Groups

	Description
Vorapaxar	Participants receive a vorapaxar 2.5 mg tablet administered orally once daily for 1 year
Placebo	Participants receive a matching placebo tablet to vorapaxar administered orally once daily for 1 year

Serious Adverse Events

	Vorapaxar	Placebo
Total, serious adverse events		
# participants affected / at risk	**0/0**	**0/0**

Other Adverse Events

Hide Other Adverse Events

Time Frame	No text entered.
Additional Description	Participant safety data collected on the eCRF for this study (SCH 530348 P05183) were limited to ocular test results. These ocular test results were not captured as adverse events, but were captured as part of outcome measures. All other participant adverse events were collected under the Study SCH 530348 P04737 (NCT00526474) parent protocol.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Vorapaxar	Participants receive a vorapaxar 2.5 mg tablet administered orally once daily for 1 year
Placebo	Participants receive a matching placebo tablet to vorapaxar administered orally once daily for 1 year

Other Adverse Events

	Vorapaxar	**Placebo**
Total, other (not including serious) adverse events		
# participants affected / at risk	**0/0**	**0/0**

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 agrees to provide to the sponsor 45 days prior to submission for publication or presentation, review copies of abstracts or manuscripts for publication that report any results of the study.

Results Point of Contact:

Name/Title: Senior Vice President, Global Clinical Development
Organization: Merck Sharp & Dohme Corp
phone: 1-800-672-6372
e-mail: ClinicalTrialsDisclosure@merck.com

No publications provided

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TO TOP

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