Telcagepant (MK-0974) Treatment of Migraine in Participants With Stable Vascular Disease (MK-0974-034)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00662818

First received: April 17, 2008
Last updated: September 3, 2015
Last verified: September 2015
History of Changes

Purpose

The purpose of this study is to evaluate the safety and efficacy of telcagepant in the treatment of acute migraine in participants with stable vascular disease. Acetaminophen/paracetamol (APAP) will be used as an active comparator in this study. The primary hypothesis of this study is that telcagepant 300 mg is superior to placebo.

Condition	Intervention	Phase
Migraine Disorders Heart Disease Cerebrovascular Accident TIA (Transient Ischemic Attack) Vascular Diseases Peripheral Vascular Diseases	Drug: Telcagepant Drug: Acetaminophen/Paracetamol Drug: Placebo to Telcagepant Drug: Placebo to Acetaminophen/Paracetamol	Phase 3

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

Official Title: A Multicenter, Randomized, Double-Blind, Placebo- and Active Controlled, Crossover Study to Evaluate the Safety and Efficacy of MK-0974 in the Treatment of Acute Migraine in Patients With Stable Vascular Disease

Resource links provided by NLM:

MedlinePlus related topics: Migraine Vascular Diseases

Drug Information available for: Acetaminophen

U.S. FDA Resources

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

Primary Outcome Measures:

- Percentage of Participants With Pain Freedom at 2 Hours Post-dose (Period 1, Migraine Attack 1) [Time Frame: 2 hours post-dose (Up to 6 weeks)] [Designated as safety issue: No]

  Pain Freedom (PF) at 2 hours post-dose (Period 1, Attack 1) defined as a decrease from a moderate or severe migraine headache (Grade 2 or 3) at baseline to no pain (Grade 0). Headache severity was subjectively rated by the participant at predefined time points on a scale of Grade 0 to Grade 3: Grade 0 - No pain; Grade 1 - Mild pain; Grade 2 - Moderate Pain; and Grade 3 - Severe Pain.

- Number of Participants Who Experienced an Adverse Event (AE) Within 14 Days Post-dose [Time Frame: Within 14 days of any dose of study medication (Up to 16 weeks)] [Designated as safety issue: Yes]

  An AE is defined as any unfavorable and unintended sign including an abnormal laboratory finding, symptom or disease associated with the use of a medical treatment or procedure, regardless of whether it is considered related to the medical treatment or procedure, that occurs during the course of the study.

- Number of Participants Discontinuing Study Drug Due to an AE Within 48 Hours Post-dose [Time Frame: Up to 48 hours post-dose (Up to 14 weeks)] [Designated as safety issue: Yes]

  An AE is defined as any unfavorable and unintended sign including an abnormal laboratory finding, symptom or disease associated with the use of a medical treatment or procedure, regardless of whether it is considered related to the medical treatment or procedure, that occurs during the course of the study.

Secondary Outcome Measures:

- Percentage of Participants With Pain Relief at 2 Hours Post-dose (Period 1, Migraine Attack 1) [Time Frame: 2 hours post-dose (Up to 6 weeks)] [Designated as safety issue: No]

  Pain Relief (PR) at 2 hours post-dose (first migraine attack), with pain relief defined as a reduction in headache severity from Grade 3/2 at baseline to Grade 1/0 at 2 hours post-dose. Headache severity was subjectively rated by the participant at predefined time points on a scale of Grade 0 to Grade 3: Grade 0 - No pain; Grade 1 - Mild pain; Grade 2 - Moderate Pain; and Grade 3 - Severe Pain.

- Number of Participants With a Confirmed Vascular Event Within 48 Hours Post-dose [Time Frame: Up to 48 hours after the dose of any study medication (Up to 14 weeks)] [Designated as safety issue: Yes]

  Confirmed Vascular Event included cardiac events, cerebrovascular events, and peripheral vascular events.

- Percentage of Participants With Absence of Phonophobia at 2 Hours Post-dose (Period 1, Migraine Attack 1) [Time Frame: 2 hours post-dose (Up to 6 weeks)] [Designated as safety issue: No]

  The participant recorded whether phonophobia (sensitivity to sound) was present or absent at each of the predefined time points.

- Percentage of Participants With Absence of Photophobia at 2 Hours Post-dose (Period 1, Migraine Attack 1) [Time Frame: 2 Hours post-dose (Up to 6 weeks)] [Designated as safety issue: No]

  The participant recorded whether photophobia (sensitivity to light) was present or absent at each of the predefined time points.

- Percentage of Participants With Absence of Nausea at 2 Hours Post-dose (Period 1, Migraine Attack 1) [Time Frame: 2 hours post-dose (Up to 6 weeks)] [Designated as safety issue: No]

  The participant recorded whether nausea was present or absent at each of the predefined time points.

- Percentage of Participants With Sustained Pain Freedom (SPF) at 2 to 24 Hours Post-dose [Time Frame: Up to 24 hours post-dose (Up to 14 weeks)] [Designated as safety issue: No]

  SPF from 2 to 24 hours post-dose is defined as PF at 2 hours, with no administration of either rescue medication or the optional second dose and with no occurrence thereafter of a mild/moderate/severe headache during the 2 to 24 hours after dosing with the study medication.

Enrollment:	165
Study Start Date:	March 2008
Study Completion Date:	September 2009
Primary Completion Date:	September 2009 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Telcagepant 300 mg→Acetaminophen/Paracetamol 1000 mg Participants receive up to 12 doses of telcagepant (280 mg tablet/capsule 300 mg), orally, and placebo to acetaminophen/paracetamol (APAP) (2- 500 mg dry filled capsules), orally, for up to 12 migraine attacks in Period 1 (6 weeks). Participants receive APAP and placebo to telcagepant for up to 12 doses, for up to 12 migraine attacks in Period 2 (6 weeks). The participant may take a blinded optional second dose of study medication or their own rescue medication if 2 hours after initial treatment, the participant still has a moderate or severe migraine headache or if the headache has returned.	Drug: Telcagepant Telcagepant (MK-0974) (300 mg soft gel capsules or 280 mg tablets) Drug: Acetaminophen/Paracetamol Acetaminophen/Paracetamol (500 mg X 2 dosage units) Drug: Placebo to Telcagepant Placebo 300 mg soft gel capsules or placebo 280 mg tablet. Drug: Placebo to Acetaminophen/Paracetamol Placebo to acetaminophen/paracetamol (500 mg X 2 dosage units)
Experimental: Placebo and APAP 1000 mg→Telcagepant 300 mg Participants receive 1 dose of placebo to APAP and placebo to telcagepant for the first migraine attack and then up to 11 doses of APAP and placebo to telcagepant for up to 11 migraine attacks in Period 1 (6 weeks). Participants receive up to 12 doses of telcagepant and placebo to APAP for up to 12 migraine attacks in Period 2 (6 weeks). The participant may take a blinded optional second dose of study medication or their own rescue medication if 2 hours after initial treatment, the participant still has a moderate or severe migraine headache or if the headache has returned.	Drug: Telcagepant Telcagepant (MK-0974) (300 mg soft gel capsules or 280 mg tablets) Drug: Acetaminophen/Paracetamol Acetaminophen/Paracetamol (500 mg X 2 dosage units) Drug: Placebo to Telcagepant Placebo 300 mg soft gel capsules or placebo 280 mg tablet. Drug: Placebo to Acetaminophen/Paracetamol Placebo to acetaminophen/paracetamol (500 mg X 2 dosage units)

Eligibility

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

Criteria

Inclusion Criteria:

- Stable coronary artery disease for 3 months or more
- 18 years of age or older with a history of migraine with or without aura
- Must use acceptable contraception throughout the study

Exclusion Criteria:

- Pregnant, breast-feeding, or planning to become pregnant during this study
- 50 years of age or older when migraines began
- Other pain syndromes that might interfere with study assessments, uncontrolled psychiatric conditions, dementia, or significant neurological disorders (other than migraine)
- History of gastric, or small intestinal surgery, or has a disease that causes malabsorption

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):

Ho TW, Ho AP, Chaitman BR, Johnson C, Mathew NT, Kost J, Fan X, Aurora SK, Brandes JL, Fei K, Beebe L, Lines C, Krucoff MW. Randomized, controlled study of telcagepant in patients with migraine and coronary artery disease. Headache. 2012 Feb;52(2):224-35. doi: 10.1111/j.1526-4610.2011.02052.x. Epub 2012 Jan 6.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00662818 History of Changes
Other Study ID Numbers:	0974-034 MK-0974-034 2007_545
Study First Received:	April 17, 2008
Results First Received:	September 5, 2014
Last Updated:	September 3, 2015
Health Authority:	United States: Food and Drug Administration

Additional relevant MeSH terms:

Ischemic Attack, Transient	Headache Disorders
Migraine Disorders	Headache Disorders, Primary
Peripheral Arterial Disease	Nervous System Diseases
Peripheral Vascular Diseases	Acetaminophen
Stroke	Analgesics
Vascular Diseases	Analgesics, Non-Narcotic
Arterial Occlusive Diseases	Antipyretics
Arteriosclerosis	Central Nervous System Agents
Atherosclerosis	Peripheral Nervous System Agents
Brain Diseases	Pharmacologic Actions
Brain Ischemia	Physiological Effects of Drugs
Cardiovascular Diseases	Sensory System Agents
Central Nervous System Diseases	Therapeutic Uses
Cerebrovascular Disorders	

ClinicalTrials.gov processed this record on April 14, 2016

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Results First Received: September 5, 2014

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Crossover Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Treatment
Conditions:	Migraine Disorders Heart Disease Cerebrovascular Accident TIA (Transient Ischemic Attack) Vascular Diseases Peripheral Vascular Diseases
Interventions:	Drug: Telcagepant Drug: Acetaminophen/Paracetamol Drug: Placebo to Telcagepant Drug: Placebo to Acetaminophen/Paracetamol

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
No text entered.

Reporting Groups

	Description
Telcagepant 300 mg→Acetaminophen/Paracetamol 1000 mg	Participants receive up to 12 doses of telcagepant (300 mg capsule/280 mg tablet), orally, and placebo to acetaminophen/paracetamol (APAP) (2- 500 mg dry filled capsules), orally, for up to 12 migraine attacks in Period 1 (6 weeks). Participants receive APAP and placebo to telcagepant for up to 12 doses, for up to 12 migraine attacks in Period 2 (6 weeks).
Placebo and APAP 1000 mg→Telcagepant 300 mg	Participants receive 1 dose of placebo to APAP and placebo to telcagepant for the first migraine attack and then up to 11 doses of APAP and placebo to telcagepant for up to 11 migraine attacks in Period 1 (6 weeks). Participants receive up to 12 doses of telcagepant and placebo to APAP for up to 12 migraine attacks in Period 2 (6 weeks).

Participant Flow for 3 periods

Period 1: Period 1 (6 Weeks)

	Telcagepant 300 mg→Acetaminophen/Paracetamol 1000 mg	Placebo and APAP 1000 mg→Telcagepant 300 mg
STARTED	**84**	**81**
Treated	**56**	**58**
COMPLETED	**56**	**58**
NOT COMPLETED	**28**	**23**

Period 2: Wash-Out (14 Days)

	Telcagepant 300 mg→Acetaminophen/Paracetamol 1000 mg	Placebo and APAP 1000 mg→Telcagepant 300 mg
STARTED	**56**	**58**
COMPLETED	**51**	**53**
NOT COMPLETED	**5**	**5**

Period 3: Period 2 (6 Weeks)

	Telcagepant 300 mg→Acetaminophen/Paracetamol 1000 mg	Placebo and APAP 1000 mg→Telcagepant 300 mg
STARTED	**51**	**53**
COMPLETED	**38**	**41**
NOT COMPLETED	**13**	**12**

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.
All treated participants

Reporting Groups

	Description
Telcagepant 300 mg→APAP 1000 mg	Participants receive up to 12 doses of telcagepant (280 mg tablet/capsule 300 mg), orally, and placebo to acetaminophen/paracetamol (APAP) (2- 500 mg dry filled capsules), orally, for up to 12 migraine attacks in Period 1 (6 weeks). Participants receive APAP and placebo to telcagepant for up to 12 doses, for up to 12 migraine attacks in Period 2 (6 weeks).
Placebo and APAP 1000 mg→Telcagepant 300 mg	Participants receive 1 dose of placebo to APAP and placebo to telcagepant for the first migraine attack and then up to 11 doses of APAP and placebo to telcagepant for up to 11 migraine attacks in Period 1 (6 weeks). Participants receive up to 12 doses of telcagepant and placebo to APAP for up to 12 migraine attacks in Period 2 (6 weeks).
Total	Total of all reporting groups

Baseline Measures

	Telcagepant 300 mg→APAP 1000 mg	**Placebo and APAP 1000 mg→Telcagepant 300 mg**	**Total**
Number of Participants [units: participants]	**56**	**58**	**114**
Age [units: Years] Mean (Standard Deviation)	**56.6 (10.1)**	**55.7 (10.0)**	**56.1 (10.0)**
Gender [units: Participants]			
Female	**33**	**36**	**69**
Male	**23**	**22**	**45**

Outcome Measures

Hide All Outcome Measures

1. Primary: Percentage of Participants With Pain Freedom at 2 Hours Post-dose (Period 1, Migraine Attack 1) [Time Frame: 2 hours post-dose (Up to 6 weeks)]

Measure Type	Primary
Measure Title	Percentage of Participants With Pain Freedom at 2 Hours Post-dose (Period 1, Migraine Attack 1)
Measure Description	Pain Freedom (PF) at 2 hours post-dose (Period 1, Attack 1) defined as a decrease from a moderate or severe migraine headache (Grade 2 or 3) at baseline to no pain (Grade 0). Headache severity was subjectively rated by the participant at predefined time points on a scale of Grade 0 to Grade 3: Grade 0 - No pain; Grade 1 - Mild pain; Grade 2 - Moderate Pain; and Grade 3 - Severe Pain.
Time Frame	2 hours post-dose (Up to 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.
The full-analysis set (FAS) included participants treated for a migraine attack. Participants had both a baseline value and at least 1 post-dose

efficacy measurement for pain severity prior to, or including, the 2-hour time point. Participants were excluded from this analysis who did not have a baseline pain score or post-dose data through 2 hours.

Reporting Groups

	Description
Telcagepant 300 mg	Participants receiving telcagepant
Placebo	Participants receiving placebo

Measured Values

	Telcagepant 300 mg	Placebo
Number of Participants Analyzed [units: participants]	**52**	**53**
Percentage of Participants With Pain Freedom at 2 Hours Post-dose (Period 1, Migraine Attack 1) [units: Percentage of participants] Number (95% Confidence Interval)	**25.0 (14.0 to 38.9)**	**18.9 (9.4 to 32.0)**

Statistical Analysis 1 for Percentage of Participants With Pain Freedom at 2 Hours Post-dose (Period 1, Migraine Attack 1)

Groups [1]	All groups
Method [2]	Regression, Logistic
P Value [3]	0.329
Odds Ratio (OR) [4]	1.62
95% Confidence Interval	0.62 to 4.25

[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:
	Computed using a logistic regression model adjusting for geographic region, baseline migraine severity, and age.
[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:
	No text entered.

2. Primary: Number of Participants Who Experienced an Adverse Event (AE) Within 14 Days Post-dose [Time Frame: Within 14 days of any dose of study medication (Up to 16 weeks)]

Measure Type	Primary
Measure Title	Number of Participants Who Experienced an Adverse Event (AE) Within 14 Days Post-dose
Measure Description	An AE is defined as any unfavorable and unintended sign including an abnormal laboratory finding, symptom or disease

	associated with the use of a medical treatment or procedure, regardless of whether it is considered related to the medical treatment or procedure, that occurs during the course of the study.
Time Frame	Within 14 days of any dose of study medication (Up to 16 weeks)
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.
All-Patients-as-Treated (APaT) population consisted of all participants who received at least 1 dose of study medication were included in the treatment group according to the medication actually received.

Reporting Groups

	Description
Telcagepant 300 mg	Participants receiving telcagepant
Acetaminophen/Paracetamol (APAP)	Participants receiving APAP

Measured Values

	Telcagepant 300 mg	**Acetaminophen/Paracetamol (APAP)**
Number of Participants Analyzed [units: participants]	**98**	**86**
Number of Participants Who Experienced an Adverse Event (AE) Within 14 Days Post-dose [units: Participants]	**21**	**14**

No statistical analysis provided for Number of Participants Who Experienced an Adverse Event (AE) Within 14 Days Post-dose

3. Primary: Number of Participants Discontinuing Study Drug Due to an AE Within 48 Hours Post-dose [Time Frame: Up to 48 hours post-dose (Up to 14 weeks)]

Measure Type	Primary
Measure Title	Number of Participants Discontinuing Study Drug Due to an AE Within 48 Hours Post-dose
Measure Description	An AE is defined as any unfavorable and unintended sign including an abnormal laboratory finding, symptom or disease associated with the use of a medical treatment or procedure, regardless of whether it is considered related to the medical treatment or procedure, that occurs during the course of the study.
Time Frame	Up to 48 hours post-dose (Up to 14 weeks)
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 APaT Population consisted of all participants who received at least 1 dose of study medication were included in the treatment group according to the medication actually received.

Reporting Groups

	Description
Telcagepant 300 mg	Participants receiving telcagepant
APAP	Participants receiving APAP

Measured Values

	Telcagepant 300 mg	APAP
Number of Participants Analyzed [units: participants]	**98**	**86**
Number of Participants Discontinuing Study Drug Due to an AE Within 48 Hours Post-dose [units: Participants]	**0**	**0**

No statistical analysis provided for Number of Participants Discontinuing Study Drug Due to an AE Within 48 Hours Post-dose

4. Secondary: Percentage of Participants With Pain Relief at 2 Hours Post-dose (Period 1, Migraine Attack 1) [Time Frame: 2 hours post-dose (Up to 6 weeks)]

Measure Type	Secondary
Measure Title	Percentage of Participants With Pain Relief at 2 Hours Post-dose (Period 1, Migraine Attack 1)
Measure Description	Pain Relief (PR) at 2 hours post-dose (first migraine attack), with pain relief defined as a reduction in headache severity from Grade 3/2 at baseline to Grade 1/0 at 2 hours post-dose. Headache severity was subjectively rated by the participant at predefined time points on a scale of Grade 0 to Grade 3: Grade 0 - No pain; Grade 1 - Mild pain; Grade 2 - Moderate Pain; and Grade 3 - Severe Pain.
Time Frame	2 hours post-dose (Up to 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.
The FAS Population included participants treated that migraine attack, and had both a baseline value and at least 1 post-dose efficacy measurement for pain severity prior to, or including, the 2-hour time point. Participants were excluded from this analysis who did not have a baseline pain score or post-dose data through 2 hours.

Reporting Groups

	Description
Telcagepant 300 mg	Participants receiving telcagepant
Placebo	Participants receiving placebo

Measured Values

	Telcagepant 300 mg	Placebo
Number of Participants Analyzed [units: participants]	**52**	**53**

Percentage of Participants With Pain Relief at 2 Hours Post-dose (Period 1, Migraine Attack 1) **[units: Percentage of Participants]** **Number (95% Confidence Interval)**	**63.5 (49.0 to 76.4)**	**56.6 (42.3 to 70.2)**

Statistical Analysis 1 for Percentage of Participants With Pain Relief at 2 Hours Post-dose (Period 1, Migraine Attack 1)

Groups [1]	All groups
Method [2]	Regression, Logistic
P Value [3]	0.420
Odds Ratio (OR) [4]	1.44
95% Confidence Interval	0.59 to 3.50

[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:
	Computed using a logistic regression model adjusting for geographic region, baseline migraine severity, and age.
[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:
	No text entered.

5. Secondary: Number of Participants With a Confirmed Vascular Event Within 48 Hours Post-dose [Time Frame: Up to 48 hours after the dose of any study medication (Up to 14 weeks)]

Measure Type	Secondary
Measure Title	Number of Participants With a Confirmed Vascular Event Within 48 Hours Post-dose
Measure Description	Confirmed Vascular Event included cardiac events, cerebrovascular events, and peripheral vascular events.
Time Frame	Up to 48 hours after the dose of any study medication (Up to 14 weeks)
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 APaT Population consisted of all participants who received at least 1 dose of study medication were included in the treatment group according to the medication actually received.

Reporting Groups

	Description
Telcagepant 300 mg	Participants receiving telcagepant

APAP	Participants receiving APAP

Measured Values

	Telcagepant 300 mg	APAP
Number of Participants Analyzed [units: participants]	**98**	**86**
Number of Participants With a Confirmed Vascular Event Within 48 Hours Post-dose [units: Participants]	**0**	**0**

No statistical analysis provided for Number of Participants With a Confirmed Vascular Event Within 48 Hours Post-dose

6. Secondary: Percentage of Participants With Absence of Phonophobia at 2 Hours Post-dose (Period 1, Migraine Attack 1) [Time Frame: 2 hours post-dose (Up to 6 weeks)]

Measure Type	Secondary
Measure Title	Percentage of Participants With Absence of Phonophobia at 2 Hours Post-dose (Period 1, Migraine Attack 1)
Measure Description	The participant recorded whether phonophobia (sensitivity to sound) was present or absent at each of the predefined time points.
Time Frame	2 hours post-dose (Up to 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.
The FAS population included participants treated that migraine attack, and had both a baseline value and at least 1 post-dose efficacy measurement for phonophobia prior to, or including, the 2-hour time point. Participants were excluded from this analysis who did not have a baseline phonophobia score or post-dose data through 2 hours.

Reporting Groups

	Description
Telcagepant 300 mg	Participants receiving telcagepant
Placebo	Participants receiving placebo

Measured Values

	Telcagepant 300 mg	Placebo
Number of Participants Analyzed [units: participants]	**52**	**53**
Percentage of Participants With Absence of Phonophobia at 2 Hours Post-dose (Period 1, Migraine Attack 1) [units: Percentage of participants] Number (95% Confidence Interval)	**65.4 (50.9 to 78.0)**	**58.5 (44.1 to 71.9)**

Statistical Analysis 1 for Percentage of Participants With Absence of Phonophobia at 2 Hours Post-dose (Period 1, Migraine Attack 1)

Groups [1]	All groups
Method [2]	Regression, Logistic
P Value [3]	0.648
Odds Ratio (OR) [4]	1.22
95% Confidence Interval	0.52 to 2.85

[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:
	Computed using a logistic regression model adjusting for geographic region, baseline migraine severity, and age.
[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:
	No text entered.

7. Secondary: Percentage of Participants With Absence of Photophobia at 2 Hours Post-dose (Period 1, Migraine Attack 1) [Time Frame: 2 Hours post-dose (Up to 6 weeks)]

Measure Type	Secondary
Measure Title	Percentage of Participants With Absence of Photophobia at 2 Hours Post-dose (Period 1, Migraine Attack 1)
Measure Description	The participant recorded whether photophobia (sensitivity to light) was present or absent at each of the predefined time points.
Time Frame	2 Hours post-dose (Up to 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.
The FAS population included participants treated that migraine attack, and had both a baseline value and at least 1 post-dose efficacy measurement for photophobia prior to, or including, the 2-hour time point. Participants were excluded from this analysis who did not have a baseline photophobia score or post-dose data through 2 hours.

Reporting Groups

	Description
Telcagepant 300 mg	Participants receiving telcagepant
Placebo	Participants receiving placebo

Measured Values

	Telcagepant 300	

	mg	Placebo
Number of Participants Analyzed [units: participants]	**52**	**53**
Percentage of Participants With Absence of Photophobia at 2 Hours Post-dose (Period 1, Migraine Attack 1) [units: Percentage of Participants] Number (95% Confidence Interval)	**53.8 (39.5 to 67.8)**	**58.5 (44.1 to 71.9)**

Statistical Analysis 1 for Percentage of Participants With Absence of Photophobia at 2 Hours Post-dose (Period 1, Migraine Attack 1)

Groups [1]	All groups
Method [2]	Regression, Logistic
P Value [3]	0.647
Odds Ratio (OR) [4]	0.80
95% Confidence Interval	0.31 to 2.07

[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:
	Computed using a logistic regression model adjusting for geographic region, baseline migraine severity, and age.
[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:
	No text entered.

8. Secondary: Percentage of Participants With Absence of Nausea at 2 Hours Post-dose (Period 1, Migraine Attack 1) [Time Frame: 2 hours post-dose (Up to 6 weeks)]

Measure Type	Secondary
Measure Title	Percentage of Participants With Absence of Nausea at 2 Hours Post-dose (Period 1, Migraine Attack 1)
Measure Description	The participant recorded whether nausea was present or absent at each of the predefined time points.
Time Frame	2 hours post-dose (Up to 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.
The FAS population included participants treated that migraine attack, and had both a baseline value and at least 1 post-dose efficacy measurement for nausea prior to, or including, the 2-hour time point. Participants were excluded from this analysis who did not have a baseline nausea score or post-dose data through 2 hours.

Reporting Groups

	Description
Telcagepant 300 mg	Participants receiving telcagepant
Placebo	Participants receiving placebo

Measured Values

	Telcagepant 300 mg	Placebo
Number of Participants Analyzed [units: participants]	**52**	**53**
Percentage of Participants With Absence of Nausea at 2 Hours Post-dose (Period 1, Migraine Attack 1) [units: Percentage of Participants] Number (95% Confidence Interval)	**80.8 (67.5 to 90.4)**	**69.8 (55.7 to 81.7)**

Statistical Analysis 1 for Percentage of Participants With Absence of Nausea at 2 Hours Post-dose (Period 1, Migraine Attack 1)

Groups [1]	All groups
Method [2]	Regression, Logistic
P Value [3]	0.201
Odds Ratio (OR) [4]	1.83
95% Confidence Interval	0.73 to 4.60

[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:
	Computed using a logistic regression model adjusting for geographic region, baseline migraine severity, and age.
[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:
	No text entered.

9. Secondary: Percentage of Participants With Sustained Pain Freedom (SPF) at 2 to 24 Hours Post-dose [Time Frame: Up to 24 hours post-dose (Up to 14 weeks)]

Measure Type	Secondary
Measure Title	Percentage of Participants With Sustained Pain Freedom (SPF) at 2 to 24 Hours Post-dose
Measure Description	SPF from 2 to 24 hours post-dose is defined as PF at 2 hours, with no administration of either rescue medication or the optional second dose and with no occurrence thereafter of a mild/moderate/severe headache during the 2 to 24 hours after dosing with the study medication.
Time Frame	Up to 24 hours post-dose (Up to 14 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.
The FAS population was participants treated that migraine attack, and had both a baseline value and at least 1 post-dose efficacy measurement for pain severity prior to, or including, the 2-hr. time point. Participants were excluded from this analysis for not having a baseline pain score, post-dose data through 24 hrs, or a recurrence question.

Reporting Groups

	Description
Telcagepant 300 mg	Participants receiving telcagepant
Placebo	Participants receiving placebo

Measured Values

	Telcagepant 300 mg	**Placebo**
Number of Participants Analyzed [units: participants]	**52**	**52**
Percentage of Participants With Sustained Pain Freedom (SPF) at 2 to 24 Hours Post-dose [units: Percentage of Participants] Number (95% Confidence Interval)	**19.2 (9.6 to 32.5)**	**15.4 (6.9 to 28.1)**

Statistical Analysis 1 for Percentage of Participants With Sustained Pain Freedom (SPF) at 2 to 24 Hours Post-dose

Groups [1]	All groups
Method [2]	Regression, Logistic
P Value [3]	0.579
Odds Ratio (OR) [4]	1.35
95% Confidence Interval	0.47 to 3.85

[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:
	Computed using a logistic regression model adjusting for geographic region, baseline migraine severity, and age.
[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:
	No text entered.

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Up to 48 hours post-dose (Up to 14 weeks)
Additional Description	No text entered.

Reporting Groups

	Description
Telcagepant	Participants receiving telcagepant
Acetaminophen/Paracetamol	Participants receiving acetaminophen/paracetamol

Serious Adverse Events

	Telcagepant	Acetaminophen/Paracetamol
Total, serious adverse events		
# participants affected / at risk	**1/98 (1.02%)**	**0/86 (0.00%)**
Psychiatric disorders		
Psychotic disorder † 1		
# participants affected / at risk	**1/98 (1.02%)**	**0/86 (0.00%)**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 12.0

Other Adverse Events

Hide Other Adverse Events

Time Frame	Up to 48 hours post-dose (Up to 14 weeks)
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Telcagepant	Participants receiving telcagepant
Acetaminophen/Paracetamol	Participants receiving acetaminophen/paracetamol

Other Adverse Events

	Telcagepant	Acetaminophen/Paracetamol
Total, other (not including serious) adverse events		
# participants affected / at risk	**0/98 (0.00%)**	**0/86 (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 sponsor must have the opportunity to review all proposed abstracts, manuscripts, or presentations regarding this study 60 days prior to submission for publication/presentation. Any information identified by the sponsor as confidential must be deleted prior to submission.

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

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

Ho TW, Ho AP, Chaitman BR, Johnson C, Mathew NT, Kost J, Fan X, Aurora SK, Brandes JL, Fei K, Beebe L, Lines C, Krucoff MW. Randomized, controlled study of telcagepant in patients with migraine and coronary artery disease. Headache. 2012 Feb;52(2):224-35. doi: 10.1111/j.1526-4610.2011.02052.x. Epub 2012 Jan 6.

Responsible Party: Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier: NCT00662818 History of Changes

Other Study ID Numbers:	0974-034 MK-0974-034 (Other Identifier: Merck Protocol Number) 2007_545 (Other Identifier: Telerx ID Number)
Study First Received:	April 17, 2008
Results First Received:	September 5, 2014
Last Updated:	September 3, 2015
Health Authority:	United States: Food and Drug Administration

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

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