Study of Telcagepant (MK-0974) in Participants With Moderate to Severe Acute Migraine With or Without Aura (MK-0974-011)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00442936

First received: February 28, 2007
Last updated: June 11, 2015
Last verified: June 2015
History of Changes

Purpose

The purpose of this study is to investigate the efficacy and safety of telcagepant (MK-0974) compared to an approved medication for acute migraine. This study was conducted as a "triple-dummy" design; for each dose of study drug, participants each received 3 forms of study drug (2 capsules of active and/or placebo and 1 tablet of active and/or placebo) and were instructed to take one of each form of study drug at dosing time.

The primary hypotheses of this study are that telcagepant is superior to placebo in Pain Freedom at 2 Hours Post-Dose, Pain Relief at 2 Hours Post-Dose, Absence of Photophobia at 2 Hours Post-Dose, Absence of Phonophobia at 2 Hours Post-Dose and Absence of Nausea at 2 Hours Post-Dose.

Condition	Intervention	Phase
Migraine	Drug: Telcagepant potassium 150 mg Drug: Telcagepant potassium 300 mg Drug: Zolmitriptan 5 mg Drug: Placebo to telcagepant 150 mg Drug: Placebo to tecagepant 300 mg Drug: Placebo to zolmitriptan 5 mg Drug: Rescue medication	Phase 3

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

Official Title: A Multicenter, Double-Blind, Placebo-Controlled, Parallel Group Study to Compare the Response to a Single Treatment With Oral MK0974 With Placebo and Comparator in Subjects With Moderate to Severe Acute Migraine With or Without Aura

Resource links provided by NLM:

MedlinePlus related topics: Headache Migraine Potassium

Drug Information available for: Zolmitriptan

U.S. FDA Resources

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

Primary Outcome Measures:

- Number of Participants With Pain Freedom (PF) at 2 Hours Post-Dose [Time Frame: 2 hours post-dose] [Designated as safety issue: No]

  Participants were asked to rate their migraine headache severity with ratings of 0=No pain, 1=Mild pain, 2=Moderate pain, and 3=Severe pain. PF at 2 hours post-dose is defined as a decrease from a moderate or severe migraine headache (Grade 2 or 3) at baseline to no pain (Grade 0) at 2 hours post-dose.

- Number of Participants With Pain Relief (PR) at 2 Hours Post-Dose [Time Frame: 2 hours post-dose] [Designated as safety issue: No]

  Participants were asked to rate their migraine headache severity with ratings of 0=No pain, 1=Mild pain, 2=Moderate pain, and 3=Severe pain. PR at 2 hours post-dose is defined as a shift from a moderate or severe migraine headache (Grade 2 or 3) at baseline to mild or no pain (Grade 1 or 0) at 2 hours post-dose.

- Number of Participants With Absence of Photophobia at 2 Hours Post-Dose [Time Frame: 2 hours post-dose] [Designated as safety issue: No]

  Participants were asked if they experienced any sensitivity to light. The number of participants who experienced no photophobia (sensitivity to light) at 2 hours post-dose was determined.

- Number of Participants With Absence of Phonophobia at 2 Hours Post-Dose [Time Frame: 2 hours post-dose] [Designated as safety issue: No]

  Participants were asked if they experienced any sensitivity to sound. The number of participants who experienced no phonophobia (sensitivity to sound) at 2 hours post-dose was determined.

- Number of Participants With Absence of Nausea at 2 Hours Post-Dose [Time Frame: 2 hours post-dose] [Designated as safety issue: No]

  Participants were asked if they experienced any nausea. The number of participants who experienced no nausea at 2 hours post-dose was determined.

- Number of Participants Who Experience At Least One Adverse Event (AE) [Time Frame: Up to 14 days after last dose of study drug] [Designated as safety issue: Yes]

  An AE is defined as any unfavorable and unintended change in the structure, function, or chemistry of the body temporally associated with the use of the study drug, whether or not considered related to the use of the product. Participants were monitored for occurrence AEs for up to 14 days after last dose study drug. Participants who took both active and placebo study drug were counted in the active group.

- Number of Participants Who Discontinue Study Drug Due to an AE [Time Frame: Up to 48 hours after first dose of study drug] [Designated as safety issue: Yes]

  An AE is defined as any unfavorable and unintended change in the structure, function, or chemistry of the body temporally associated with the use of the study drug, whether or not considered related to the use of the product. Participants who took both active and placebo study drug were counted in the active group.

Secondary Outcome Measures:

- Number of Participants With Sustained Pain Freedom (SPF) From 2 to 24 Hours Post-Dose [Time Frame: 2 to 24 hours post-dose] [Designated as safety issue: No]

  SPF is defined as PF at 2 hours post-dose with no return of mild/moderate/severe headache through 24 hours post-dose, and with no administration of either the optional second dose of study drug or any rescue medication between 2 and 24 hours post-dose.

- Number of Participants With Total Migraine Freedom (TMF) at 2 Hours Post-Dose [Time Frame: 2 hours post-dose] [Designated as safety issue: No]

  TMF at 2 hours post-dose is defined as PF at 2 hours post-dose without any of the following migraine-related symptoms: phonophobia, photophobia, nausea or vomiting at 2 hours post-dose.

- Number of Participants With Total Migraine Freedom (TMF) at 2 to 24 Hours Post-Dose [Time Frame: 2 to 24 hours post-dose] [Designated as safety issue: No]

  TMF at 2 to 24 hours post-dose is defined as TMF at 2 hours post-dose with no administration of either the optional second dose of study drug or any rescue medication between 2 and 24 hours post-dose, no return of mild/moderate/severe headache within 24 hours and no presence of phonophobia, photophobia, nausea or vomiting within 24 hours post-dose.

Enrollment: 1380
Study Start Date: February 2007
Study Completion Date: October 2007
Primary Completion Date: October 2007 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Telcagepant 150 mg Participants receive telcagepant 150 mg capsules, one capsule administered orally at initial onset of moderate to severe migraine headache. If, after 2 hours post-dose, participants still have a moderate to severe migraine or migraine recurs, participants may receive an optional second dose of study drug (telcagepant 150 mg or placebo) or one dose of non-study rescue medication.	Drug: Telcagepant potassium 150 mg Telcagepant 150 mg liquid-filled soft gel capsules Drug: Placebo to tecagepant 300 mg Placebo to match tecagepant 300 mg liquid-filled soft gel capsules Drug: Placebo to zolmitriptan 5 mg Placebo to match zolmitriptan 5 mg tablets Drug: Rescue medication If moderate or severe migraine headache pain continues or recurs 2 hours after dose of study drug, participants are allowed to take an optional second dose of study drug or their own non-study rescue migraine medication, which may include analgesics (e.g., nonsteroidal anti-inflammatory drugs [NSAIDs] or opiates), anti-emetics, or zolmitriptan. Triptans other than zolmitriptan and ergot derivatives are prohibited for 24 hours following the last dose of study drug.
Experimental: Telcagepant 300 mg Participants receive telcagepant 300 mg capsules, one capsule administered orally at initial onset of moderate to severe migraine headache. If, after 2 hours post-dose, participants still have a moderate to severe migraine or migraine recurs, participants may receive an optional second dose of study drug (telcagepant 300 mg or placebo) or one dose of non-study rescue medication.	Drug: Telcagepant potassium 300 mg Telcagepant 300 mg liquid-filled soft gel capsules Drug: Placebo to telcagepant 150 mg Placebo to match telcagepant 150 mg liquid-filled soft gel capsules Drug: Placebo to zolmitriptan 5 mg Placebo to match zolmitriptan 5 mg tablets Drug: Rescue medication If moderate or severe migraine headache pain continues or recurs 2 hours after dose of study drug, participants are allowed to take an optional second dose of study drug or their own non-study rescue migraine medication, which may include analgesics (e.g., nonsteroidal anti-inflammatory drugs [NSAIDs] or opiates), anti-emetics, or zolmitriptan. Triptans other than zolmitriptan and ergot derivatives are prohibited for 24 hours following the last dose of study drug.
Active Comparator: Zolmitriptan 5 mg Participants receive zolmitriptan 5 mg tablets, one tablet administered orally at initial onset of moderate to severe migraine headache. If, after 2 hours post-dose, participants still have a moderate to severe migraine or migraine recurs, participants may receive an optional second dose of study drug (placebo) or one dose of non-study rescue medication.	Drug: Zolmitriptan 5 mg Zolmitriptan 5 mg tablets Drug: Placebo to telcagepant 150 mg Placebo to match telcagepant 150 mg liquid-filled soft gel capsules Drug: Placebo to tecagepant 300 mg Placebo to match tecagepant 300 mg liquid-filled soft gel capsules Drug: Rescue medication If moderate or severe migraine headache pain continues or recurs 2 hours after dose of study drug, participants are allowed to take an optional second dose of study drug or their own non-study rescue migraine medication, which may include analgesics (e.g., nonsteroidal anti-inflammatory drugs [NSAIDs] or opiates), anti-emetics, or zolmitriptan. Triptans other than zolmitriptan and ergot derivatives are prohibited for 24 hours following the last dose of study drug.
Placebo Comparator: Placebo	Drug: Placebo to telcagepant 150 mg

Participants receive placebo matching capsules or tablets, one capsule or tablet administered orally at initial onset of moderate to severe migraine headache. If, after 2 hours post-dose, participants still have a moderate to severe migraine or migraine recurs, participants may receive an optional second dose of study drug (placebo) or one dose of non-study rescue medication.	Placebo to match telcagepant 150 mg liquid-filled soft gel capsules Drug: Placebo to tecagepant 300 mg Placebo to match tecagepant 300 mg liquid-filled soft gel capsules Drug: Placebo to zolmitriptan 5 mg Placebo to match zolmitriptan 5 mg tablets Drug: Rescue medication If moderate or severe migraine headache pain continues or recurs 2 hours after dose of study drug, participants are allowed to take an optional second dose of study drug or their own non-study rescue migraine medication, which may include analgesics (e.g., nonsteroidal anti-inflammatory drugs [NSAIDs] or opiates), anti-emetics, or zolmitriptan. Triptans other than zolmitriptan and ergot derivatives are prohibited for 24 hours following the last dose of study drug.

Eligibility

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

Criteria

Inclusion Criteria:

- Has at least 1 year history of migraine (with or without aura)
- Females of child bearing potential must use acceptable contraception throughout trial.

Exclusion Criteria:

- Is pregnant/breast-feeding (or is a female expecting to conceive during study period)
- Has history or evidence of stroke/transient ischemic attacks, heart disease, coronary artery vasospasm, other significant underlying cardiovascular diseases, uncontrolled hypertension (high blood pressure), uncontrolled diabetes, or human immunodeficiency virus (HIV) disease
- Has major depression, other pain syndromes that might interfere with study assessments, psychiatric conditions, dementia, or significant neurological disorders (other than migraine)
- Has a history of gastric, or small intestinal surgery, or has a disease that causes malabsorption
- Has a history of cancer within the last 5 years.

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: NCT00442936

Sponsors and Collaborators

Merck Sharp & Dohme Corp.

Investigators

Study Director: Medical Monitor Merck Sharp & Dohme Corp.

More Information

Publications:

Ho TW, Ferrari MD, Dodick DW, Galet V, Kost J, Fan X, Leibensperger H, Froman S, Assaid C, Lines C, Koppen H, Winner PK. Efficacy and tolerability of MK-0974 (telcagepant), a new oral antagonist of calcitonin gene-related peptide receptor, compared with zolmitriptan for acute

migraine: a randomised, placebo-controlled, parallel-treatment trial. Lancet. 2008 Dec 20;372(9656):2115-23. doi: 10.1016/S0140-6736(08)61626-8. Epub 2008 Nov 25.

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

Ho TW, Olesen J, Dodick DW, Kost J, Lines C, Ferrari MD. Antimigraine efficacy of telcagepant based on patient's historical triptan response. Headache. 2011 Jan;51(1):64-72. doi: 10.1111/j.1526-4610.2010.01790.x. Epub 2010 Nov 4.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00442936 History of Changes
Other Study ID Numbers:	0974-011 MK-0974-011 2006_525
Study First Received:	February 28, 2007
Results First Received:	June 17, 2014
Last Updated:	June 11, 2015
Health Authority:	United States: Food and Drug Administration

Additional relevant MeSH terms:

Migraine Disorders	Molecular Mechanisms of Pharmacological Action
Brain Diseases	Neurotransmitter Agents
Central Nervous System Diseases	Pharmacologic Actions
Headache Disorders	Physiological Effects of Drugs
Headache Disorders, Primary	Protein Synthesis Inhibitors
Nervous System Diseases	Serotonin 5-HT1 Receptor Agonists
Oxazolidinones	Serotonin Agents
Zolmitriptan	Serotonin Receptor Agonists
Anti-Infective Agents	Therapeutic Uses
Enzyme Inhibitors	

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First received: February 28, 2007
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History of Changes

Results First Received: June 17, 2014

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Treatment
Condition:	Migraine
Interventions:	Drug: Telcagepant potassium 150 mg Drug: Telcagepant potassium 300 mg Drug: Zolmitriptan 5 mg Drug: Placebo to telcagepant 150 mg Drug: Placebo to tecagepant 300 mg Drug: Placebo to zolmitriptan 5 mg Drug: Rescue medication

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 150 mg	Participants receive telcagepant 150 mg capsules, one capsule administered orally at initial onset of moderate to severe migraine headache. If, after 2 hours post-dose, participants still have a moderate to severe migraine or migraine recurs, participants may receive an optional second dose of study drug (telcagepant 150 mg or placebo) or one dose of non-study rescue medication.
Telcagepant 300 mg	Participants receive telcagepant 300 mg capsules, one capsule administered orally at initial onset of moderate to severe migraine headache. If, after 2 hours post-dose, participants still have a moderate to severe migraine or migraine recurs, participants may receive an optional second dose of study drug (telcagepant 300 mg or placebo) or one dose of non-study rescue medication.
Zolmitriptan 5 mg	Participants receive zolmitriptan 5 mg tablets, one tablet administered orally at initial onset of moderate to severe migraine headache. If, after 2 hours post-dose, participants still have a moderate to severe migraine or migraine recurs, participants may receive an optional second dose of study drug (placebo) or one dose of non-study rescue medication.
Placebo	Participants receive placebo matching capsules or tablets, one capsule or tablet administered orally at initial onset of moderate to severe migraine headache. If, after 2 hours post-dose, participants still have a moderate to severe migraine or migraine recurs, participants may receive an optional second dose of study drug (placebo) or one dose of non-study rescue medication.

Participant Flow: Overall Study

	Telcagepant 150 mg	Telcagepant 300 mg	Zolmitriptan 5 mg	Placebo
STARTED	**333**	**354**	**345**	**348**
COMPLETED	**332**	**354**	**344**	**347**
NOT COMPLETED	**1**	**0**	**1**	**1**
Protocol Violation	**1**	**0**	**1**	**1**

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
Telcagepant 150 mg	Participants receive telcagepant 150 mg capsules, one capsule administered orally at initial onset of moderate to severe migraine headache. If, after 2 hours post-dose, participants still have a moderate to severe migraine or migraine recurs, participants may receive an optional second dose of study drug (telcagepant 150 mg or placebo) or one dose of non-study rescue medication.
Telcagepant 300 mg	Participants receive telcagepant 300 mg capsules, one capsule administered orally at initial onset of moderate to severe migraine headache. If, after 2 hours post-dose, participants still have a moderate to severe migraine or migraine recurs, participants may receive an optional second dose of study drug (telcagepant 300 mg or placebo) or one dose of non-study rescue medication.
Zolmitriptan 5 mg	Participants receive zolmitriptan 5 mg tablets, one tablet administered orally at initial onset of moderate to severe

	migraine headache. If, after 2 hours post-dose, participants still have a moderate to severe migraine or migraine recurs, participants may receive an optional second dose of study drug (placebo) or one dose of non-study rescue medication.
Placebo	Participants receive placebo matching capsules or tablets, one capsule or tablet administered orally at initial onset of moderate to severe migraine headache. If, after 2 hours post-dose, participants still have a moderate to severe migraine or migraine recurs, participants may receive an optional second dose of study drug (placebo) or one dose of non-study rescue medication.
Total	Total of all reporting groups

Baseline Measures

	Telcagepant 150 mg	Telcagepant 300 mg	Zolmitriptan 5 mg	Placebo	Total
Number of Participants [units: participants]	333	354	345	348	1380
Age [units: Years] Mean (Standard Deviation)	42.7 (11.2)	42.6 (11.4)	41.7 (11.7)	42.3 (11.6)	42.3 (11.4)
Gender [units: Participants]					
Female	277	300	298	294	1169
Male	56	54	47	54	211

Outcome Measures

Hide All Outcome Measures

1. Primary: Number of Participants With Pain Freedom (PF) at 2 Hours Post-Dose [Time Frame: 2 hours post-dose]

Measure Type	Primary
Measure Title	Number of Participants With Pain Freedom (PF) at 2 Hours Post-Dose
Measure Description	Participants were asked to rate their migraine headache severity with ratings of 0=No pain, 1=Mild pain, 2=Moderate pain, and 3=Severe pain. PF at 2 hours post-dose is defined as a decrease from a moderate or severe migraine headache (Grade 2 or 3) at baseline to no pain (Grade 0) at 2 hours post-dose.
Time Frame	2 hours post-dose
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 population consisted of all participants who were randomized, took at least one dose of study drug, recorded a baseline pain score, and had at least one pain score measurement within 2 hours post-dose.

Reporting Groups

	Description
Telcagepant 150 mg	Participants receive telcagepant 150 mg capsules, one capsule administered orally at initial onset of moderate to severe migraine headache. If, after 2 hours post-dose, participants still have a moderate to severe migraine or migraine recurs, participants may receive an optional second dose of study drug (telcagepant 150 mg or placebo) or one dose of non-study rescue medication.
Telcagepant 300 mg	Participants receive telcagepant 300 mg capsules, one capsule administered orally at initial onset of moderate to severe

	migraine headache. If, after 2 hours post-dose, participants still have a moderate to severe migraine or migraine recurs, participants may receive an optional second dose of study drug (telcagepant 300 mg or placebo) or one dose of non-study rescue medication.
Zolmitriptan 5 mg	Participants receive zolmitriptan 5 mg tablets, one tablet administered orally at initial onset of moderate to severe migraine headache. If, after 2 hours post-dose, participants still have a moderate to severe migraine or migraine recurs, participants may receive an optional second dose of study drug (placebo) or one dose of non-study rescue medication.
Placebo	Participants receive placebo matching capsules or tablets, one capsule or tablet administered orally at initial onset of moderate to severe migraine headache. If, after 2 hours post-dose, participants still have a moderate to severe migraine or migraine recurs, participants may receive an optional second dose of study drug (placebo) or one dose of non-study rescue medication.

Measured Values

	Telcagepant 150 mg	Telcagepant 300 mg	Zolmitriptan 5 mg	Placebo
Number of Participants Analyzed [units: participants]	**317**	**338**	**328**	**328**
Number of Participants With Pain Freedom (PF) at 2 Hours Post-Dose [units: Participants]	**56**	**89**	**101**	**29**

Statistical Analysis 1 for Number of Participants With Pain Freedom (PF) at 2 Hours Post-Dose

Groups [1]	Telcagepant 150 mg vs. Placebo
Method [2]	Regression, Logistic
P Value [3]	<0.001
Odds Ratio (OR) [4]	2.26
95% Confidence Interval	1.40 to 3.66

[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:
	From logistic model adjusting for geographic region, baseline migraine severity, and age. An odds ratio >1 is in favor of the first treatment group of the corresponding pairwise comparison.

Statistical Analysis 2 for Number of Participants With Pain Freedom (PF) at 2 Hours Post-Dose

Groups [1]	Telcagepant 300 mg vs. Placebo
Method [2]	Regression, Logistic
P Value [3]	<0.001

Odds Ratio (OR) [4]	3.81
95% Confidence Interval	2.42 to 6.00

[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:
	From logistic model adjusting for geographic region, baseline migraine severity, and age. An odds ratio >1 is in favor of the first treatment group of the corresponding pairwise comparison.

2. Primary: Number of Participants With Pain Relief (PR) at 2 Hours Post-Dose [Time Frame: 2 hours post-dose]

Measure Type	Primary
Measure Title	Number of Participants With Pain Relief (PR) at 2 Hours Post-Dose
Measure Description	Participants were asked to rate their migraine headache severity with ratings of 0=No pain, 1=Mild pain, 2=Moderate pain, and 3=Severe pain. PR at 2 hours post-dose is defined as a shift from a moderate or severe migraine headache (Grade 2 or 3) at baseline to mild or no pain (Grade 1 or 0) at 2 hours post-dose.
Time Frame	2 hours post-dose
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 population consisted of all participants who were randomized, took at least one dose of study drug, recorded a baseline pain score, and had at least one pain score measurement within 2 hours post-dose.

Reporting Groups

	Description
Telcagepant 150 mg	Participants receive telcagepant 150 mg capsules, one capsule administered orally at initial onset of moderate to severe migraine headache. If, after 2 hours post-dose, participants still have a moderate to severe migraine or migraine recurs, participants may receive an optional second dose of study drug (telcagepant 150 mg or placebo) or one dose of non-study rescue medication.
Telcagepant 300 mg	Participants receive telcagepant 300 mg capsules, one capsule administered orally at initial onset of moderate to severe migraine headache. If, after 2 hours post-dose, participants still have a moderate to severe migraine or migraine recurs, participants may receive an optional second dose of study drug (telcagepant 300 mg or placebo) or one dose of non-study rescue medication.
Zolmitriptan 5 mg	Participants receive zolmitriptan 5 mg tablets, one tablet administered orally at initial onset of moderate to severe migraine headache. If, after 2 hours post-dose, participants still have a moderate to severe migraine or migraine recurs, participants may receive an optional second dose of study drug (placebo) or one dose of non-study rescue medication.
Placebo	Participants receive placebo matching capsules or tablets, one capsule or tablet administered orally at initial onset of moderate to severe migraine headache. If, after 2 hours post-dose, participants still have a moderate to severe migraine

	or migraine recurs, participants may receive an optional second dose of study drug (placebo) or one dose of non-study rescue medication.

Measured Values

	Telcagepant 150 mg	Telcagepant 300 mg	Zolmitriptan 5 mg	Placebo
Number of Participants Analyzed [units: participants]	**317**	**338**	**328**	**328**
Number of Participants With Pain Relief (PR) at 2 Hours Post-Dose [units: Participants]	**157**	**183**	**185**	**88**

Statistical Analysis 1 for Number of Participants With Pain Relief (PR) at 2 Hours Post-Dose

Groups [1]	Telcagepant 150 mg vs. Placebo
Method [2]	Regression, Logistic
P Value [3]	<0.001
Odds Ratio (OR) [4]	2.82
95% Confidence Interval	2.02 to 3.95

[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:
	From logistic model adjusting for geographic region, baseline migraine severity, and age. An odds ratio >1 is in favor of the first treatment group of the corresponding pairwise comparison.

Statistical Analysis 2 for Number of Participants With Pain Relief (PR) at 2 Hours Post-Dose

Groups [1]	Telcagepant 300 mg vs. Placebo
Method [2]	Regression, Logistic
P Value [3]	<0.001
Odds Ratio (OR) [4]	3.44
95% Confidence Interval	2.47 to 4.79

[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:
	From logistic model adjusting for geographic region, baseline migraine severity, and age. An odds ratio >1 is in favor of the first treatment group of the corresponding pairwise comparison.

3. Primary: Number of Participants With Absence of Photophobia at 2 Hours Post-Dose [Time Frame: 2 hours post-dose]

Measure Type	Primary
Measure Title	Number of Participants With Absence of Photophobia at 2 Hours Post-Dose
Measure Description	Participants were asked if they experienced any sensitivity to light. The number of participants who experienced no photophobia (sensitivity to light) at 2 hours post-dose was determined.
Time Frame	2 hours post-dose
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 population consisted of all participants who were randomized, took at least one dose of study drug, recorded a baseline photophobia assessment, and had at least one photophobia assessment within 2 hours post-dose.

Reporting Groups

	Description
Telcagepant 150 mg	Participants receive telcagepant 150 mg capsules, one capsule administered orally at initial onset of moderate to severe migraine headache. If, after 2 hours post-dose, participants still have a moderate to severe migraine or migraine recurs, participants may receive an optional second dose of study drug (telcagepant 150 mg or placebo) or one dose of non-study rescue medication.
Telcagepant 300 mg	Participants receive telcagepant 300 mg capsules, one capsule administered orally at initial onset of moderate to severe migraine headache. If, after 2 hours post-dose, participants still have a moderate to severe migraine or migraine recurs, participants may receive an optional second dose of study drug (telcagepant 300 mg or placebo) or one dose of non-study rescue medication.
Zolmitriptan 5 mg	Participants receive zolmitriptan 5 mg tablets, one tablet administered orally at initial onset of moderate to severe migraine headache. If, after 2 hours post-dose, participants still have a moderate to severe migraine or migraine recurs, participants may receive an optional second dose of study drug (placebo) or one dose of non-study rescue medication.
Placebo	Participants receive placebo matching capsules or tablets, one capsule or tablet administered orally at initial onset of moderate to severe migraine headache. If, after 2 hours post-dose, participants still have a moderate to severe migraine or migraine recurs, participants may receive an optional second dose of study drug (placebo) or one dose of non-study rescue medication.

Measured Values

	Telcagepant 150 mg	**Telcagepant 300 mg**	**Zolmitriptan 5 mg**	**Placebo**
Number of Participants Analyzed [units: participants]	**317**	**338**	**328**	**327**

Number of Participants With Absence of Photophobia at 2 Hours Post-Dose [units: Participants]	**143**	**169**	**163**	**92**

Statistical Analysis 1 for Number of Participants With Absence of Photophobia at 2 Hours Post-Dose

Groups [1]	Telcagepant 150 mg vs. Placebo
Method [2]	Regression, Logistic
P Value [3]	<0.001
Odds Ratio (OR) [4]	2.14
95% Confidence Interval	1.54 to 2.97

[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:
	From logistic model adjusting for geographic region, baseline migraine severity, and age. An odds ratio >1 is in favor of the first treatment group of the corresponding pairwise comparison.

Statistical Analysis 2 for Number of Participants With Absence of Photophobia at 2 Hours Post-Dose

Groups [1]	Telcagepant 300 mg vs. Placebo
Method [2]	Regression, Logistic
P Value [3]	<0.001
Odds Ratio (OR) [4]	2.61
95% Confidence Interval	1.89 to 3.61

[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:
	From logistic model adjusting for geographic region, baseline migraine severity, and age. An odds ratio >1 is in favor of the first treatment group of the corresponding pairwise comparison.

4. Primary: Number of Participants With Absence of Phonophobia at 2 Hours Post-Dose [Time Frame: 2 hours post-dose]

Measure Type	Primary
Measure Title	Number of Participants With Absence of Phonophobia at 2 Hours Post-Dose
Measure Description	Participants were asked if they experienced any sensitivity to sound. The number of participants who experienced no phonophobia (sensitivity to sound) at 2 hours post-dose was determined.
Time Frame	2 hours post-dose
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 population consisted of all participants who were randomized, took at least one dose of study drug, recorded a baseline phonophobia assessment, and had at least one phonophobia assessment within 2 hours post-dose.

Reporting Groups

	Description
Telcagepant 150 mg	Participants receive telcagepant 150 mg capsules, one capsule administered orally at initial onset of moderate to severe migraine headache. If, after 2 hours post-dose, participants still have a moderate to severe migraine or migraine recurs, participants may receive an optional second dose of study drug (telcagepant 150 mg or placebo) or one dose of non-study rescue medication.
Telcagepant 300 mg	Participants receive telcagepant 300 mg capsules, one capsule administered orally at initial onset of moderate to severe migraine headache. If, after 2 hours post-dose, participants still have a moderate to severe migraine or migraine recurs, participants may receive an optional second dose of study drug (telcagepant 300 mg or placebo) or one dose of non-study rescue medication.
Zolmitriptan 5 mg	Participants receive zolmitriptan 5 mg tablets, one tablet administered orally at initial onset of moderate to severe migraine headache. If, after 2 hours post-dose, participants still have a moderate to severe migraine or migraine recurs, participants may receive an optional second dose of study drug (placebo) or one dose of non-study rescue medication.
Placebo	Participants receive placebo matching capsules or tablets, one capsule or tablet administered orally at initial onset of moderate to severe migraine headache. If, after 2 hours post-dose, participants still have a moderate to severe migraine or migraine recurs, participants may receive an optional second dose of study drug (placebo) or one dose of non-study rescue medication.

Measured Values

	Telcagepant 150 mg	**Telcagepant 300 mg**	**Zolmitriptan 5 mg**	**Placebo**
Number of Participants Analyzed [units: participants]	**317**	**338**	**326**	**327**
Number of Participants With Absence of Phonophobia at 2 Hours Post-Dose [units: Participants]	**170**	**193**	**180**	**120**

Statistical Analysis 1 for Number of Participants With Absence of Phonophobia at 2 Hours Post-Dose

Groups [1]	Telcagepant 150 mg vs. Placebo
Method [2]	Regression, Logistic

P Value [3]	<0.001
Odds Ratio (OR) [4]	2.05
95% Confidence Interval	1.49 to 2.82

[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:
	From logistic model adjusting for geographic region, baseline migraine severity, and age. An odds ratio >1 is in favor of the first treatment group of the corresponding pairwise comparison.

Statistical Analysis 2 for Number of Participants With Absence of Phonophobia at 2 Hours Post-Dose

Groups [1]	Telcagepant 300 mg vs. Placebo
Method [2]	Regression, Logistic
P Value [3]	<0.001
Odds Ratio (OR) [4]	2.37
95% Confidence Interval	1.73 to 3.25

[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:
	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:
	From logistic model adjusting for geographic region, baseline migraine severity, and age. An odds ratio >1 is in favor of the first treatment group of the corresponding pairwise comparison.

5. Primary: Number of Participants With Absence of Nausea at 2 Hours Post-Dose [Time Frame: 2 hours post-dose]

Measure Type	Primary
Measure Title	Number of Participants With Absence of Nausea at 2 Hours Post-Dose
Measure Description	Participants were asked if they experienced any nausea. The number of participants who experienced no nausea at 2 hours post-dose was determined.
Time Frame	2 hours post-dose

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 population consisted of all participants who were randomized, took at least one dose of study drug, recorded a baseline nausea assessment, and had at least one nausea assessment within 2 hours post-dose.

Reporting Groups

	Description
Telcagepant 150 mg	Participants receive telcagepant 150 mg capsules, one capsule administered orally at initial onset of moderate to severe migraine headache. If, after 2 hours post-dose, participants still have a moderate to severe migraine or migraine recurs, participants may receive an optional second dose of study drug (telcagepant 150 mg or placebo) or one dose of non-study rescue medication.
Telcagepant 300 mg	Participants receive telcagepant 300 mg capsules, one capsule administered orally at initial onset of moderate to severe migraine headache. If, after 2 hours post-dose, participants still have a moderate to severe migraine or migraine recurs, participants may receive an optional second dose of study drug (telcagepant 300 mg or placebo) or one dose of non-study rescue medication.
Zolmitriptan 5 mg	Participants receive zolmitriptan 5 mg tablets, one tablet administered orally at initial onset of moderate to severe migraine headache. If, after 2 hours post-dose, participants still have a moderate to severe migraine or migraine recurs, participants may receive an optional second dose of study drug (placebo) or one dose of non-study rescue medication.
Placebo	Participants receive placebo matching capsules or tablets, one capsule or tablet administered orally at initial onset of moderate to severe migraine headache. If, after 2 hours post-dose, participants still have a moderate to severe migraine or migraine recurs, participants may receive an optional second dose of study drug (placebo) or one dose of non-study rescue medication.

Measured Values

	Telcagepant 150 mg	**Telcagepant 300 mg**	**Zolmitriptan 5 mg**	**Placebo**
Number of Participants Analyzed [units: participants]	**316**	**337**	**327**	**327**
Number of Participants With Absence of Nausea at 2 Hours Post-Dose [units: Participants]	**212**	**218**	**232**	**179**

Statistical Analysis 1 for Number of Participants With Absence of Nausea at 2 Hours Post-Dose

Groups [1]	Telcagepant 150 mg vs. Placebo
Method [2]	Regression, Logistic
P Value [3]	<0.001
Odds Ratio (OR) [4]	1.73
95% Confidence Interval	1.25 to 2.39

[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:
	From logistic model adjusting for geographic region, baseline migraine severity, and age. An odds ratio >1 is in favor of the first treatment group of the corresponding pairwise comparison.

Statistical Analysis 2 for Number of Participants With Absence of Nausea at 2 Hours Post-Dose

Groups [1]	Telcagepant 300 mg vs. Placebo
Method [2]	Regression, Logistic
P Value [3]	0.006
Odds Ratio (OR) [4]	1.55
95% Confidence Interval	1.13 to 2.13

[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:
	From logistic model adjusting for geographic region, baseline migraine severity, and age. An odds ratio >1 is in favor of the first treatment group of the corresponding pairwise comparison.

6. Primary: Number of Participants Who Experience At Least One Adverse Event (AE) [Time Frame: Up to 14 days after last dose of study drug]

Measure Type	Primary
Measure Title	Number of Participants Who Experience At Least One Adverse Event (AE)
Measure Description	An AE is defined as any unfavorable and unintended change in the structure, function, or chemistry of the body temporally associated with the use of the study drug, whether or not considered related to the use of the product. Participants were monitored for occurrence AEs for up to 14 days after last dose study drug. Participants who took both active and placebo study drug were counted in the active group.
Time Frame	Up to 14 days after last dose of study drug
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 population consisted of all participants who received at least one dose of study drug. Participants were included in the treatment arm corresponding to the study treatment actually taken at the time of the AE.

Reporting Groups

	Description
Telcagepant 150 mg	Participants receive telcagepant 150 mg capsules, one capsule administered orally at initial onset of moderate to severe migraine headache. If, after 2 hours post-dose, participants still have a moderate to severe migraine or migraine recurs, participants may receive an optional second dose of study drug (telcagepant 150 mg or placebo) or one dose of non-study rescue medication.
Telcagepant 300 mg	Participants receive telcagepant 300 mg capsules, one capsule administered orally at initial onset of moderate to severe migraine headache. If, after 2 hours post-dose, participants still have a moderate to severe migraine or migraine recurs, participants may receive an optional second dose of study drug (telcagepant 300 mg or placebo) or one dose of non-study rescue medication.
Zolmitriptan 5 mg	Participants receive zolmitriptan 5 mg tablets, one tablet administered orally at initial onset of moderate to severe migraine headache. If, after 2 hours post-dose, participants still have a moderate to severe migraine or migraine recurs, participants may receive an optional second dose of study drug (placebo) or one dose of non-study rescue medication.
Placebo	Participants receive placebo matching capsules or tablets, one capsule or tablet administered orally at initial onset of moderate to severe migraine headache. If, after 2 hours post-dose, participants still have a moderate to severe migraine or migraine recurs, participants may receive an optional second dose of study drug (placebo) or one dose of non-study rescue medication.

Measured Values

	Telcagepant 150 mg	Telcagepant 300 mg	Zolmitriptan 5 mg	Placebo
Number of Participants Analyzed [units: participants]	**334**	**352**	**345**	**349**
Number of Participants Who Experience At Least One Adverse Event (AE) [units: Participants]	**105**	**131**	**175**	**112**

No statistical analysis provided for Number of Participants Who Experience At Least One Adverse Event (AE)

7. Primary: Number of Participants Who Discontinue Study Drug Due to an AE [Time Frame: Up to 48 hours after first dose of study drug]

Measure Type	Primary
Measure Title	Number of Participants Who Discontinue Study Drug Due to an AE
Measure Description	An AE is defined as any unfavorable and unintended change in the structure, function, or chemistry of the body temporally associated with the use of the study drug, whether or not considered related to the use of the product. Participants who took both active and placebo study drug were counted in the active group.
Time Frame	Up to 48 hours after first dose of study drug
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 populaton consisted of all participants who received at least one dose of study drug. Participants were included in the treatment arm corresponding to the study treatment actually taken at the time of the AE.

Reporting Groups

	Description
Telcagepant 150 mg	Participants receive telcagepant 150 mg capsules, one capsule administered orally at initial onset of moderate to severe migraine headache. If, after 2 hours post-dose, participants still have a moderate to severe migraine or migraine recurs, participants may receive an optional second dose of study drug (telcagepant 150 mg or placebo) or one dose of non-study rescue medication.
Telcagepant 300 mg	Participants receive telcagepant 300 mg capsules, one capsule administered orally at initial onset of moderate to severe migraine headache. If, after 2 hours post-dose, participants still have a moderate to severe migraine or migraine recurs, participants may receive an optional second dose of study drug (telcagepant 300 mg or placebo) or one dose of non-study rescue medication.
Zolmitriptan 5 mg	Participants receive zolmitriptan 5 mg tablets, one tablet administered orally at initial onset of moderate to severe migraine headache. If, after 2 hours post-dose, participants still have a moderate to severe migraine or migraine recurs, participants may receive an optional second dose of study drug (placebo) or one dose of non-study rescue medication.
Placebo	Participants receive placebo matching capsules or tablets, one capsule or tablet administered orally at initial onset of moderate to severe migraine headache. If, after 2 hours post-dose, participants still have a moderate to severe migraine or migraine recurs, participants may receive an optional second dose of study drug (placebo) or one dose of non-study rescue medication.

Measured Values

	Telcagepant 150 mg	Telcagepant 300 mg	Zolmitriptan 5 mg	Placebo
Number of Participants Analyzed [units: participants]	**334**	**352**	**345**	**349**
Number of Participants Who Discontinue Study Drug Due to an AE [units: Participants]	**0**	**0**	**0**	**0**

No statistical analysis provided for Number of Participants Who Discontinue Study Drug Due to an AE

8. Secondary: Number of Participants With Sustained Pain Freedom (SPF) From 2 to 24 Hours Post-Dose [Time Frame: 2 to 24 hours post-dose]

Measure Type	Secondary
Measure Title	Number of Participants With Sustained Pain Freedom (SPF) From 2 to 24 Hours Post-Dose
Measure Description	SPF is defined as PF at 2 hours post-dose with no return of mild/moderate/severe headache through 24 hours post-dose, and with no administration of either the optional second dose of study drug or any rescue medication between 2 and 24 hours post-dose.
Time Frame	2 to 24 hours post-dose
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 population consisted of all participants who were randomized, took at least one dose of study drug, recorded a baseline pain score, had at least one pain score measurement within 2 hours post-dose, and had at least one pain score measurement at between 2 and 24 hours post-dose.

Reporting Groups

	Description

Telcagepant 150 mg	Participants receive telcagepant 150 mg capsules, one capsule administered orally at initial onset of moderate to severe migraine headache. If, after 2 hours post-dose, participants still have a moderate to severe migraine or migraine recurs, participants may receive an optional second dose of study drug (telcagepant 150 mg or placebo) or one dose of non-study rescue medication.
Telcagepant 300 mg	Participants receive telcagepant 300 mg capsules, one capsule administered orally at initial onset of moderate to severe migraine headache. If, after 2 hours post-dose, participants still have a moderate to severe migraine or migraine recurs, participants may receive an optional second dose of study drug (telcagepant 300 mg or placebo) or one dose of non-study rescue medication.
Zolmitriptan 5 mg	Participants receive zolmitriptan 5 mg tablets, one tablet administered orally at initial onset of moderate to severe migraine headache. If, after 2 hours post-dose, participants still have a moderate to severe migraine or migraine recurs, participants may receive an optional second dose of study drug (placebo) or one dose of non-study rescue medication.
Placebo	Participants receive placebo matching capsules or tablets, one capsule or tablet administered orally at initial onset of moderate to severe migraine headache. If, after 2 hours post-dose, participants still have a moderate to severe migraine or migraine recurs, participants may receive an optional second dose of study drug (placebo) or one dose of non-study rescue medication.

Measured Values

	Telcagepant 150 mg	Telcagepant 300 mg	Zolmitriptan 5 mg	Placebo
Number of Participants Analyzed [units: participants]	**314**	**336**	**328**	**328**
Number of Participants With Sustained Pain Freedom (SPF) From 2 to 24 Hours Post-Dose [units: Participants]	**34**	**66**	**59**	**14**

Statistical Analysis 1 for Number of Participants With Sustained Pain Freedom (SPF) From 2 to 24 Hours Post-Dose

Groups [1]	Telcagepant 150 mg vs. Placebo
Method [2]	Regression, Logistic
P Value [3]	0.002
Odds Ratio (OR) [4]	2.80
95% Confidence Interval	1.47 to 5.35

[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:
	From logistic model adjusting for geographic region, baseline migraine severity, and age. An odds ratio >1 is in favor of the first treatment group of the corresponding pairwise comparison.

Statistical Analysis 2 for Number of Participants With Sustained Pain Freedom (SPF) From 2 to 24 Hours Post-Dose

Groups [1]	Telcagepant 300 mg vs. Placebo
Method [2]	Regression, Logistic
P Value [3]	<0.001
Odds Ratio (OR) [4]	5.75
95% Confidence Interval	3.15 to 10.51

[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:
	From logistic model adjusting for geographic region, baseline migraine severity, and age. An odds ratio >1 is in favor of the first treatment group of the corresponding pairwise comparison.

9. Secondary: Number of Participants With Total Migraine Freedom (TMF) at 2 Hours Post-Dose [Time Frame: 2 hours post-dose]

Measure Type	Secondary
Measure Title	Number of Participants With Total Migraine Freedom (TMF) at 2 Hours Post-Dose
Measure Description	TMF at 2 hours post-dose is defined as PF at 2 hours post-dose without any of the following migraine-related symptoms: phonophobia, photophobia, nausea or vomiting at 2 hours post-dose.
Time Frame	2 hours post-dose
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 population consisted of all participants who were randomized, took at least one dose of study drug, recorded a baseline pain score, had at least one pain score measurement within 2 hours post-dose, and had at least one assessment for phonophobia, photophobia, nausea and vomiting within 2 hours post-dose.

Reporting Groups

	Description
Telcagepant 150 mg	Participants receive telcagepant 150 mg capsules, one capsule administered orally at initial onset of moderate to severe migraine headache. If, after 2 hours post-dose, participants still have a moderate to severe migraine or migraine recurs, participants may receive an optional second dose of study drug (telcagepant 150 mg or placebo) or one dose of non-study rescue medication.
Telcagepant 300 mg	Participants receive telcagepant 300 mg capsules, one capsule administered orally at initial onset of moderate to severe migraine headache. If, after 2 hours post-dose, participants still have a moderate to severe migraine or migraine recurs, participants may receive an optional second dose of study drug (telcagepant 300 mg or placebo) or one dose of non-study rescue medication.

Zolmitriptan 5 mg	Participants receive zolmitriptan 5 mg tablets, one tablet administered orally at initial onset of moderate to severe migraine headache. If, after 2 hours post-dose, participants still have a moderate to severe migraine or migraine recurs, participants may receive an optional second dose of study drug (placebo) or one dose of non-study rescue medication.
Placebo	Participants receive placebo matching capsules or tablets, one capsule or tablet administered orally at initial onset of moderate to severe migraine headache. If, after 2 hours post-dose, participants still have a moderate to severe migraine or migraine recurs, participants may receive an optional second dose of study drug (placebo) or one dose of non-study rescue medication.

Measured Values

	Telcagepant 150 mg	Telcagepant 300 mg	Zolmitriptan 5 mg	Placebo
Number of Participants Analyzed [units: participants]	**317**	**338**	**328**	**328**
Number of Participants With Total Migraine Freedom (TMF) at 2 Hours Post-Dose [units: Participants]	**43**	**76**	**87**	**27**

Statistical Analysis 1 for Number of Participants With Total Migraine Freedom (TMF) at 2 Hours Post-Dose

Groups [1]	Telcagepant 150 mg vs. Placebo
Method [2]	Regression, Logistic
P Value [3]	0.026
Odds Ratio (OR) [4]	1.78
95% Confidence Interval	1.07 to 2.97

[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:
	From logistic model adjusting for geographic region, baseline migraine severity, and age. An odds ratio >1 is in favor of the first treatment group of the corresponding pairwise comparison.

Statistical Analysis 2 for Number of Participants With Total Migraine Freedom (TMF) at 2 Hours Post-Dose

Groups [1]	Telcagepant 300 mg vs. Placebo
Method [2]	Regression, Logistic
P Value [3]	<0.001
Odds Ratio (OR) [4]	3.34
95% Confidence Interval	2.08 to 5.35

[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:
	From logistic model adjusting for geographic region, baseline migraine severity, and age. An odds ratio >1 is in favor of the first treatment group of the corresponding pairwise comparison.

10. Secondary: Number of Participants With Total Migraine Freedom (TMF) at 2 to 24 Hours Post-Dose [Time Frame: 2 to 24 hours post-dose]

Measure Type	Secondary
Measure Title	Number of Participants With Total Migraine Freedom (TMF) at 2 to 24 Hours Post-Dose
Measure Description	TMF at 2 to 24 hours post-dose is defined as TMF at 2 hours post-dose with no administration of either the optional second dose of study drug or any rescue medication between 2 and 24 hours post-dose, no return of mild/moderate/severe headache within 24 hours and no presence of phonophobia, photophobia, nausea or vomiting within 24 hours post-dose.
Time Frame	2 to 24 hours post-dose
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 population consisted of all participants who were randomized, took at least one dose of study drug, recorded a baseline pain score, had at least one pain score measurement within 2 to 24 hours post-dose, and had at least one assessment for phonophobia, photophobia, nausea and vomiting within 2 to 24 hours post-dose.

Reporting Groups

	Description
Telcagepant 150 mg	Participants receive telcagepant 150 mg capsules, one capsule administered orally at initial onset of moderate to severe migraine headache. If, after 2 hours post-dose, participants still have a moderate to severe migraine or migraine recurs, participants may receive an optional second dose of study drug (telcagepant 150 mg or placebo) or one dose of non-study rescue medication.
Telcagepant 300 mg	Participants receive telcagepant 300 mg capsules, one capsule administered orally at initial onset of moderate to severe migraine headache. If, after 2 hours post-dose, participants still have a moderate to severe migraine or migraine recurs, participants may receive an optional second dose of study drug (telcagepant 300 mg or placebo) or one dose of non-study rescue medication.
Zolmitriptan 5 mg	Participants receive zolmitriptan 5 mg tablets, one tablet administered orally at initial onset of moderate to severe migraine headache. If, after 2 hours post-dose, participants still have a moderate to severe migraine or migraine recurs, participants may receive an optional second dose of study drug (placebo) or one dose of non-study rescue medication.
Placebo	Participants receive placebo matching capsules or tablets, one capsule or tablet administered orally at initial onset of moderate to severe migraine headache. If, after 2 hours post-dose, participants still have a moderate to severe migraine or migraine recurs, participants may receive an optional second dose of study drug (placebo) or one dose of non-study rescue medication.

Measured Values

	Telcagepant 150 mg	Telcagepant 300 mg	Zolmitriptan 5 mg	Placebo
Number of Participants Analyzed [units: participants]	**315**	**336**	**328**	**328**
Number of Participants With Total Migraine Freedom (TMF) at 2 to 24 Hours Post-Dose [units: Participants]	**26**	**57**	**51**	**13**

Statistical Analysis 1 for Number of Participants With Total Migraine Freedom (TMF) at 2 to 24 Hours Post-Dose

Groups [1]	Telcagepant 150 mg vs. Placebo
Method [2]	Regression, Logistic
P Value [3]	0.021
Odds Ratio (OR) [4]	2.25
95% Confidence Interval	1.13 to 4.47

[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:
	From logistic model adjusting for geographic region, baseline migraine severity, and age. An odds ratio >1 is in favor of the first treatment group of the corresponding pairwise comparison.

Statistical Analysis 2 for Number of Participants With Total Migraine Freedom (TMF) at 2 to 24 Hours Post-Dose

Groups [1]	Telcagepant 300 mg vs. Placebo
Method [2]	Regression, Logistic
P Value [3]	<0.001
Odds Ratio (OR) [4]	5.21
95% Confidence Interval	2.78 to 9.76

[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:
	From logistic model adjusting for geographic region, baseline migraine severity, and age. An odds ratio >1 is in favor of the first treatment group of the corresponding pairwise comparison.

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Up to 14 days after last dose of study drug
Additional Description	The All Participants as Treated population consisted of all participants who received at least 1 dose of study drug. Participants were included in the treatment arm corresponding to the study treatment actually taken at the time of the AE.

Reporting Groups

	Description
Telcagepant 150 mg	Participants receive telcagepant 150 mg capsules, one capsule administered orally at initial onset of moderate to severe migraine headache. If, after 2 hours post-dose, participants still have a moderate to severe migraine or migraine recurs, participants may receive an optional second dose of study drug (telcagepant 150 mg or placebo) or one dose of non-study rescue medication.
Telcagepant 300 mg	Participants receive telcagepant 300 mg capsules, one capsule administered orally at initial onset of moderate to severe migraine headache. If, after 2 hours post-dose, participants still have a moderate to severe migraine or migraine recurs, participants may receive an optional second dose of study drug (telcagepant 300 mg or placebo) or one dose of non-study rescue medication.
Zolmitriptan 5 mg	Participants receive zolmitriptan 5 mg tablets, one tablet administered orally at initial onset of moderate to severe migraine headache. If, after 2 hours post-dose, participants still have a moderate to severe migraine or migraine recurs, participants may receive an optional second dose of study drug (placebo) or one dose of non-study rescue medication.
Placebo	Participants receive placebo matching capsules or tablets, one capsule or tablet administered orally at initial onset of moderate to severe migraine headache. If, after 2 hours post-dose, participants still have a moderate to severe migraine or migraine recurs, participants may receive an optional second dose of study drug (placebo) or one dose of non-study rescue medication.

Serious Adverse Events

	Telcagepant 150 mg	Telcagepant 300 mg	Zolmitriptan 5 mg	Placebo
Total, serious adverse events				
# participants affected / at risk	**0/334 (0.00%)**	**0/352 (0.00%)**	**0/345 (0.00%)**	**1/349 (0.29%)**
Musculoskeletal and connective tissue disorders				
Sensation of heaviness † 1				
# participants affected / at risk	**0/334 (0.00%)**	**0/352 (0.00%)**	**0/345 (0.00%)**	**1/349 (0.29%)**

† Events were collected by systematic assessment

1 Term from vocabulary, MedDRA 10.1

Other Adverse Events

Hide Other Adverse Events

Time Frame	Up to 14 days after last dose of study drug
Additional Description	The All Participants as Treated population consisted of all participants who received at least 1 dose of study drug. Participants were included in the treatment arm corresponding to the study treatment actually taken at the time of the AE.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Telcagepant 150 mg	Participants receive telcagepant 150 mg capsules, one capsule administered orally at initial onset of moderate to severe migraine headache. If, after 2 hours post-dose, participants still have a moderate to severe migraine or migraine recurs, participants may receive an optional second dose of study drug (telcagepant 150 mg or placebo) or one dose of non-study rescue medication.
Telcagepant 300 mg	Participants receive telcagepant 300 mg capsules, one capsule administered orally at initial onset of moderate to severe migraine headache. If, after 2 hours post-dose, participants still have a moderate to severe migraine or migraine recurs, participants may receive an optional second dose of study drug (telcagepant 300 mg or placebo) or one dose of non-study rescue medication.
Zolmitriptan 5 mg	Participants receive zolmitriptan 5 mg tablets, one tablet administered orally at initial onset of moderate to severe migraine headache. If, after 2 hours post-dose, participants still have a moderate to severe migraine or migraine recurs, participants may receive an optional second dose of study drug (placebo) or one dose of non-study rescue medication.
Placebo	Participants receive placebo matching capsules or tablets, one capsule or tablet administered orally at initial onset of moderate to severe migraine headache. If, after 2 hours post-dose, participants still have a moderate to severe migraine or migraine recurs, participants may receive an optional second dose of study drug (placebo) or one dose of non-study rescue medication.

Other Adverse Events

	Telcagepant 150 mg	Telcagepant 300 mg	Zolmitriptan 5 mg	Placebo
Total, other (not including serious) adverse events				
# participants affected / at risk	**66/334 (19.76%)**	**74/352 (21.02%)**	**107/345 (31.01%)**	**54/349 (15.47%)**
Gastrointestinal disorders				
Dry mouth † 1				
# participants affected / at risk	**18/334 (5.39%)**	**21/352 (5.97%)**	**28/345 (8.12%)**	**13/349 (3.72%)**
Nausea † 1				
# participants affected / at risk	**13/334 (3.89%)**	**17/352 (4.83%)**	**20/345 (5.80%)**	**13/349 (3.72%)**
General disorders				
Fatigue † 1				
# participants affected / at risk	**14/334 (4.19%)**	**15/352 (4.26%)**	**24/345 (6.96%)**	**8/349 (2.29%)**
Nervous system disorders				
Dizziness † 1				

# participants affected / at risk	**15/334 (4.49%)**	**19/352 (5.40%)**	**38/345 (11.01%)**	**20/349 (5.73%)**
Paraesthesia † 1				
# participants affected / at risk	**4/334 (1.20%)**	**6/352 (1.70%)**	**18/345 (5.22%)**	**5/349 (1.43%)**
Somnolence † 1				
# participants affected / at risk	**15/334 (4.49%)**	**19/352 (5.40%)**	**20/345 (5.80%)**	**14/349 (4.01%)**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 10.1

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.

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:

Ho TW, Ferrari MD, Dodick DW, Galet V, Kost J, Fan X, Leibensperger H, Froman S, Assaid C, Lines C, Koppen H, Winner PK. Efficacy and tolerability of MK-0974 (telcagepant), a new oral antagonist of calcitonin gene-related peptide receptor, compared with zolmitriptan for acute migraine: a randomised, placebo-controlled, parallel-treatment trial. Lancet. 2008 Dec 20;372(9656):2115-23. doi: 10.1016/S0140-6736(08)61626-8. Epub 2008 Nov 25.

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

Ho TW, Olesen J, Dodick DW, Kost J, Lines C, Ferrari MD. Antimigraine efficacy of telcagepant based on patient's historical triptan response. Headache. 2011 Jan;51(1):64-72. doi: 10.1111/j.1526-4610.2010.01790.x. Epub 2010 Nov 4.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00442936 History of Changes
Other Study ID Numbers:	0974-011 MK-0974-011 (Other Identifier: Merck Protocol Number) 2006_525 (Other Identifier: Telerx ID Number)
Study First Received:	February 28, 2007
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Last Updated:	June 11, 2015
Health Authority:	United States: Food and Drug Administration

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