Telcagepant (MK-0974) Long-Term Safety Study in Adult Participants With Acute Migraine (MK-0974-012)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00443209

First received: February 28, 2007
Last updated: July 13, 2015
Last verified: July 2015
History of Changes

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

Purpose

The purpose of this study is to investigate the safety and tolerability of telcagepant (MK-0974) in the long-term treatment of acute migraine in adult participants. The primary hypothesis of this study is that telcagepant is well tolerated in the long-term treatment of acute migraine in adult participants.

Condition	Intervention	Phase
Migraine	Drug: Telcagepant 300 mg soft gel capsules Drug: Telcagepant 280 mg tablets Drug: Rizatriptan 10 mg tablets Drug: Placebo to telcagepant capsules Drug: Placebo to telcagepant tablets Drug: Placebo to rizatriptan tablets	Phase 3

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

Official Title: A Multicenter, Double-Blind, Active-Controlled, Parallel Group Study to Examine the Safety, Tolerability and Efficacy of Oral MK-0974 for the Long Term Treatment of Acute Migraine With or Without Aura

Resource links provided by NLM:

MedlinePlus related topics: Migraine

Drug Information available for: Rizatriptan Rizatriptan benzoate

U.S. FDA Resources

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

Primary Outcome Measures:

- Percentage of Participants With At Least One Triptan-Related Adverse Experience (AE) [Time Frame: Within 14 days of any dose of study drug (Up to 18.5 months)] [Designated as safety issue: Yes]

  Triptan-related AEs are defined as: chest pain, chest tightness, asthenia, paraesthesia, dysaesthesia or hyperaesthesia. Participants were monitored for triptan-related AEs for 14 days after any dose of study drug.

- Percentage of Participants With At Least One Clinical AE [Time Frame: Within 14 days of any dose of study drug (Up to 18.5 months)] [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 product, whether or not considered related to the use of the product. Any worsening (i.e., any clinically significant adverse change in frequency and/or intensity) of a preexisting condition which is temporally associated with the use of the study product, is also an AE. A clinical AE was an AE reported as a result of a clinical examination. Participants were monitored for clinical AEs for 14 days after any dose of study drug.

- Percentage of Participants With At Least One Laboratory AE [Time Frame: Within 14 days of any dose of study drug (Up to 18.5 months)] [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 product, whether or not considered related to the use of the product. Any worsening (i.e., any clinically significant adverse change in frequency and/or intensity) of a preexisting condition which is temporally associated with the use of the study product, is also an AE. A laboratory AE was an AE reported as a result of a laboratory assessment or test. Participants were monitored for laboratory AEs for 14 days after any dose of study drug.

- Percentage of Participants With At Least One Vital Sign Measurement Outside Predefined Limits of Change [Time Frame: Within 14 days of any dose of study drug (Up to 18.5 months)] [Designated as safety issue: Yes]

  Predefined limits of change were established for vital sign measurements: Systolic Blood Pressure (>=180 mm Hg and 20 mm Hg increase OR <=90 mm Hg and 20 mm Hg decrease), Diastolic Blood Pressure (>=105 mm Hg and 15 mm Hg increase OR <=50 mm Hg and 15 mm Hg decrease), Pulse (>=120 beats per minute [bpm] and 15 bpm increase OR <=50 bpm and 15 bpm decrease), Body Temperature (>38º C [oral equivalent]) and Respiratory Rate (>25 or increase of 10 OR <5 or decrease of 10 [per minute]). Participants were monitored for vital sign measurements outside predefined limits of change for 14 days after any dose of study drug.

Secondary Outcome Measures:

- Percentage of Participant Migraine Attacks With Pain Freedom (PF) at 2 Hours Post-Dose [Time Frame: 2 hours post-dose (Up to 18 months)] [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 mild, moderate or severe migraine headache (Grade 1, 2, or 3) at baseline to no pain (Grade 0) 2 hours post-dose.

Enrollment:	1068
Study Start Date:	February 2007
Study Completion Date:	January 2009
Primary Completion Date:	January 2009 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Telcagepant 280 mg/300 mg Participants receive telcagepant 300 mg soft gel capsules or telcagepant 280 mg tablets, administered orally as a single dose at onset of migraine. If still experiencing a migraine 2 hours after the first dose of telcagepant, participants may take an optional second dose of study drug or non-study rescue medication. Participants may take up to 16 doses (for treatment of up to 8 migraines) of telcagepant per month for up to 18 months.	Drug: Telcagepant 300 mg soft gel capsules One capsule taken orally at onset of migraine Drug:

	Telcagepant 280 mg tablets One tablet taken orally at onset of migraine Drug: Placebo to rizatriptan tablets One tablet taken orally at onset of migraine
Active Comparator: Rizatriptan 10 mg Participants receive rizatriptan tablets, administered orally as a single dose at onset of migraine. If still experiencing a migraine 2 hours after the first dose of rizatriptan, participants may take an optional second dose of study drug or non-study rescue medication. Participants may take up to 16 doses (for treatment of up to 8 migraines) of rizatriptan per month for up to 18 months.	Drug: Rizatriptan 10 mg tablets One tablet taken orally at onset of migraine Drug: Placebo to telcagepant capsules One capsule taken orally at onset of migraine Drug: Placebo to telcagepant tablets One tablet taken orally at onset of migraine

Eligibility

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

Criteria

Inclusion Criteria:

- At least 1 year history of migraine (with or without aura)
- Females of child bearing potential must use acceptable contraception throughout trial
- In general good health based on screening assessment

Exclusion Criteria:

- Pregnant/breast-feeding (or is a female expecting to conceive during study period)
- 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
- Major depression, other pain syndromes that might interfere with study assessments, psychiatric conditions, dementia, or significant

neurological disorders (other than migraine)
- History of gastric, or small intestinal surgery, or has a disease that causes malabsorption
- 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: NCT00443209

Sponsors and Collaborators

Merck Sharp & Dohme Corp.

Investigators

Study Director: Medical Director Merck Sharp & Dohme Corp.

More Information

Publications:

Connor KM, Aurora SK, Loeys T, Ashina M, Jones C, Giezek H, Massaad R, Williams-Diaz A, Lines C, Ho TW. Long-term tolerability of telcagepant for acute treatment of migraine in a randomized trial. Headache. 2011 Jan;51(1):73-84. doi: 10.1111/j.1526-4610.2010.01799.x. Epub 2010 Nov 10.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00443209 History of Changes
Other Study ID Numbers:	0974-012 MK-0974-012 2006_524
Study First Received:	February 28, 2007
Results First Received:	July 29, 2014
Last Updated:	July 13, 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	Serotonin Agents
Nervous System Diseases	Serotonin Receptor Agonists
Rizatriptan	

ClinicalTrials.gov processed this record on April 14, 2016

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Results First Received: July 29, 2014

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Treatment
Condition:	Migraine
Interventions:	Drug: Telcagepant 300 mg soft gel capsules Drug: Telcagepant 280 mg tablets Drug: Rizatriptan 10 mg tablets Drug: Placebo to telcagepant capsules Drug: Placebo to telcagepant tablets Drug: Placebo to rizatriptan tablets

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
The trial was considered to have achieved completion as defined by the treatment of 100 participants for 12 months.

Reporting Groups

	Description
Telcagepant 280 mg/300 mg	Participants receive telcagepant 300 mg soft gel capsules or telcagepant 280 mg tablets, administered orally as a single dose at onset of migraine. If still experiencing a migraine 2 hours after the first dose of telcagepant, participants may take an optional second dose of study drug or non-study rescue medication. Participants may take up to 16 doses (for treatment of up to 8 migraines) of telcagepant per month for up to 18 months.
Rizatriptan 10 mg	Participants receive rizatriptan tablets, administered orally as a single dose at onset of migraine. If still experiencing a migraine 2 hours after the first dose of rizatriptan, participants may take an optional second dose of study drug or non-study rescue medication. Participants may take up to 16 doses (for treatment of up to 8 migraines) of rizatriptan per month for up to 18 months.

Participant Flow for 2 periods

Period 1: Months 1 to 12 Treatment Period

	Telcagepant 280 mg/300 mg	Rizatriptan 10 mg
STARTED	712	356
Treated	641	313
COMPLETED	367 [1]	202 [1]
NOT COMPLETED	345	154
Adverse Event	22	11
Protocol Violation	14	7
Lack of Efficacy	50	11
Lack of Qualifying Event	1	1
Lost to Follow-up	36	15
Physician Decision	8	4
Pregnancy	3	4
Trial Terminated	43	23
Withdrawal by Subject	95	34
Missing	2	1
Not Treated	71	43

[1] Trial terminated used for participants not completing 12 months of treatment due to trial completion

Period 2: Months 13 to 18 Treatment Period

	Telcagepant 280 mg/300 mg	Rizatriptan 10 mg
STARTED	186 [1]	86 [2]
COMPLETED	87 [3]	39 [3]
NOT COMPLETED	99	47
Adverse Event	1	0
Protocol Violation	1	0
Lack of Efficacy	1	0

Lost to Follow-up	**2**	**2**
Trial Terminated	**87**	**43**
Withdrawal by Subject	**7**	**2**

[1] The Months 13 to 18 Treatment Period.was optional. 181 participants chose not to continue.
[2] The Months 13 to 18 Treatment Period was optional. 116 participants chose not to continue.
[3] Trial terminated used for participants not completing 18 months of treatment due to trial completion

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.
Baseline Analyis Population consisted of All Treated Participants.

Reporting Groups

	Description
Telcagepant 280 mg/300 mg	Participants receive telcagepant 300 mg soft gel capsules or telcagepant 280 mg tablets, administered orally as a single dose at onset of migraine. If still experiencing a migraine 2 hours after the first dose of telcagepant, participants may take an optional second dose of study drug or non-study rescue medication. Participants may take up to 16 doses (for treatment of up to 8 migraines) of telcagepant per month for up to 18 months.
Rizatriptan 10 mg	Participants receive rizatriptan tablets, administered orally as a single dose at onset of migraine. If still experiencing a migraine 2 hours after the first dose of rizatriptan, participants may take an optional second dose of study drug or non-study rescue medication. Participants may take up to 16 doses (for treatment of up to 8 migraines) of rizatriptan per month for up to 18 months.
Total	Total of all reporting groups

Baseline Measures

	Telcagepant 280 mg/300 mg	**Rizatriptan 10 mg**	**Total**
Number of Participants [units: participants]	**641**	**313**	**954**
Age [units: Years] Mean (Standard Deviation)	**42.5 (10.9)**	**41.9 (11.1)**	**42.3 (11.0)**
Gender [units: Participants]			
Female	**502**	**237**	**739**
Male	**139**	**76**	**215**

Outcome Measures

Hide All Outcome Measures

1. Primary: Percentage of Participants With At Least One Triptan-Related Adverse Experience (AE) [Time Frame: Within 14 days of any dose of study drug (Up to 18.5 months)]

Measure Type	Primary
Measure Title	Percentage of Participants With At Least One Triptan-Related Adverse Experience (AE)
Measure Description	Triptan-related AEs are defined as: chest pain, chest tightness, asthenia, paraesthesia, dysaesthesia or hyperaesthesia. Participants were monitored for triptan-related AEs for 14 days after any dose of study drug.
Time Frame	Within 14 days of any dose of study drug (Up to 18.5 months)
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The All-Patients-As-Treated (APAT) population consisted of all participants who received at least one dose of study drug.

Reporting Groups

	Description
Telcagepant 280 mg/300 mg	Participants receive telcagepant 300 mg soft gel capsules or telcagepant 280 mg tablets, administered orally as a single dose at onset of migraine. If still experiencing a migraine 2 hours after the first dose of telcagepant, participants may take an optional second dose of study drug or non-study rescue medication. Participants may take up to 16 doses (for treatment of up to 8 migraines) of telcagepant per month for up to 18 months.
Rizatriptan 10 mg	Participants receive rizatriptan tablets, administered orally as a single dose at onset of migraine. If still experiencing a migraine 2 hours after the first dose of rizatriptan, participants may take an optional second dose of study drug or non-study rescue medication. Participants may take up to 16 doses (for treatment of up to 8 migraines) of rizatriptan per month for up to 18 months.

Measured Values

	Telcagepant 280 mg/300 mg	**Rizatriptan 10 mg**
Number of Participants Analyzed [units: participants]	**641**	**313**
Percentage of Participants With At Least One Triptan-Related Adverse Experience (AE) [units: Percentage of Participants]	**5.0**	**11.2**

Statistical Analysis 1 for Percentage of Participants With At Least One Triptan-Related Adverse Experience (AE)

Groups [1]	All groups
Method [2]	Miettenen and Nurminen method
P Value [3]	<0.001
Treatment Difference [4]	-6.2
95% Confidence Interval	-10.4 to -2.6

[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:
	Treatment Difference was compared using the Miettinen and Nurminen (MN) method.

2. Primary: Percentage of Participants With At Least One Clinical AE [Time Frame: Within 14 days of any dose of study drug (Up to 18.5 months)]

Measure Type	Primary
Measure Title	Percentage of Participants With At Least One Clinical 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 product, whether or not considered related to the use of the product. Any worsening (i.e., any clinically significant adverse change in frequency and/or intensity) of a preexisting condition which is temporally associated with the use of the study product, is also an AE. A clinical AE was an AE reported as a result of a clinical examination. Participants were monitored for clinical AEs for 14 days after any dose of study drug.
Time Frame	Within 14 days of any dose of study drug (Up to 18.5 months)
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The APAT population consisted of all participants who received at least one dose of study drug.

Reporting Groups

	Description
Telcagepant 280 mg/300 mg	Participants receive telcagepant 300 mg soft gel capsules or telcagepant 280 mg tablets, administered orally as a single dose at onset of migraine. If still experiencing a migraine 2 hours after the first dose of telcagepant, participants may take an optional second dose of study drug or non-study rescue medication. Participants may take up to 16 doses (for treatment of up to 8 migraines) of telcagepant per month for up to 18 months.
Rizatriptan 10 mg	Participants receive rizatriptan tablets, administered orally as a single dose at onset of migraine. If still experiencing a migraine 2 hours after the first dose of rizatriptan, participants may take an optional second dose of study drug or non-study rescue medication. Participants may take up to 16 doses (for treatment of up to 8 migraines) of rizatriptan per month for up to 18 months.

Measured Values

	Telcagepant 280 mg/300 mg	**Rizatriptan 10 mg**
Number of Participants Analyzed [units: participants]	**641**	**313**
Percentage of Participants With At Least One Clinical AE [units: Percentage of Participants]	**58.7**	**63.9**

Statistical Analysis 1 for Percentage of Participants With At Least One Clinical AE

Groups [1]	All groups

Treatment Difference [2]	-5.2
95% Confidence Interval	-11.7 to 1.4

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant estimation information:
	Treatment Difference was compared using the MN method.

3. Primary: Percentage of Participants With At Least One Laboratory AE [Time Frame: Within 14 days of any dose of study drug (Up to 18.5 months)]

Measure Type	Primary
Measure Title	Percentage of Participants With At Least One Laboratory 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 product, whether or not considered related to the use of the product. Any worsening (i.e., any clinically significant adverse change in frequency and/or intensity) of a preexisting condition which is temporally associated with the use of the study product, is also an AE. A laboratory AE was an AE reported as a result of a laboratory assessment or test. Participants were monitored for laboratory AEs for 14 days after any dose of study drug.
Time Frame	Within 14 days of any dose of study drug (Up to 18.5 months)
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The APAT population consisted of all participants who received at least one dose of study drug.

Reporting Groups

	Description
Telcagepant 280 mg/300 mg	Participants receive telcagepant 300 mg soft gel capsules or telcagepant 280 mg tablets, administered orally as a single dose at onset of migraine. If still experiencing a migraine 2 hours after the first dose of telcagepant, participants may take an optional second dose of study drug or non-study rescue medication. Participants may take up to 16 doses (for treatment of up to 8 migraines) of telcagepant per month for up to 18 months.
Rizatriptan 10 mg	Participants receive rizatriptan tablets, administered orally as a single dose at onset of migraine. If still experiencing a migraine 2 hours after the first dose of rizatriptan, participants may take an optional second dose of study drug or non-study rescue medication. Participants may take up to 16 doses (for treatment of up to 8 migraines) of rizatriptan per month for up to 18 months.

Measured Values

	Telcagepant 280 mg/300 mg	**Rizatriptan 10 mg**
Number of Participants Analyzed [units: participants]	**641**	**313**
Percentage of Participants With At Least One Laboratory AE [units: Percentage of Participants]	**1.9**	**1.6**

Statistical Analysis 1 for Percentage of Participants With At Least One Laboratory AE

Groups [1]	All groups
Treatment Difference [2]	0.3
95% Confidence Interval	-2.0 to 2.0

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant estimation information:
	Treatment Difference was compared using the MN method.

4. Primary: Percentage of Participants With At Least One Vital Sign Measurement Outside Predefined Limits of Change [Time Frame: Within 14 days of any dose of study drug (Up to 18.5 months)]

Measure Type	Primary
Measure Title	Percentage of Participants With At Least One Vital Sign Measurement Outside Predefined Limits of Change
Measure Description	Predefined limits of change were established for vital sign measurements: Systolic Blood Pressure (>=180 mm Hg and 20 mm Hg increase OR <=90 mm Hg and 20 mm Hg decrease), Diastolic Blood Pressure (>=105 mm Hg and 15 mm Hg increase OR <=50 mm Hg and 15 mm Hg decrease), Pulse (>=120 beats per minute [bpm] and 15 bpm increase OR <=50 bpm and 15 bpm decrease), Body Temperature (>38º C [oral equivalent]) and Respiratory Rate (>25 or increase of 10 OR <5 or decrease of 10 [per minute]). Participants were monitored for vital sign measurements outside predefined limits of change for 14 days after any dose of study drug.
Time Frame	Within 14 days of any dose of study drug (Up to 18.5 months)
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The APAT population consisted of all participants who received at least one dose of study drug.

Reporting Groups

	Description
Telcagepant 280 mg/300 mg	Participants receive telcagepant 300 mg soft gel capsules or telcagepant 280 mg tablets, administered orally as a single dose at onset of migraine. If still experiencing a migraine 2 hours after the first dose of telcagepant, participants may take an optional second dose of study drug or non-study rescue medication. Participants may take up to 16 doses (for treatment of up to 8 migraines) of telcagepant per month for up to 18 months.
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Measured Values

	Telcagepant 280 mg/300 mg	**Rizatriptan 10 mg**
Number of Participants Analyzed [units: participants]	**641**	**313**

Percentage of Participants With At Least One Vital Sign Measurement Outside Predefined Limits of Change [units: Percentage of Participants]		
Systolic Blood Pressure Increase	**0.2**	**0.3**
Systolic Blood Pressure Decrease	**1.4**	**1.3**
Diastolic Blood Pressure Increase	**0.3**	**0.6**
Diastolic Blood Pressure Decrease	**1.1**	**1.0**
Pulse Increase	**0.0**	**0.0**
Pulse Decrease	**0.6**	**1.6**
Body Temperature Increase	**0.3**	**0.3**
Respiratory Rate Increase or Decrease	**0.8**	**0.6**

No statistical analysis provided for Percentage of Participants With At Least One Vital Sign Measurement Outside Predefined Limits of Change

5. Secondary: Percentage of Participant Migraine Attacks With Pain Freedom (PF) at 2 Hours Post-Dose [Time Frame: 2 hours post-dose (Up to 18 months)]

Measure Type	Secondary
Measure Title	Percentage of Participant Migraine Attacks 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 mild, moderate or severe migraine headache (Grade 1, 2, or 3) at baseline to no pain (Grade 0) 2 hours post-dose.
Time Frame	2 hours post-dose (Up to 18 months)
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) population consisted of all participants who were randomized and reported at least one treated migraine attack with at least one post-treatment efficacy evaluation.

Reporting Groups

	Description
Telcagepant 280 mg/300 mg	Participants receive telcagepant 300 mg soft gel capsules or telcagepant 280 mg tablets, administered orally as a single dose at onset of migraine. If still experiencing a migraine 2 hours after the first dose of telcagepant, participants may take an optional second dose of study drug or non-study rescue medication. Participants may take up to 16 doses (for treatment of up to 8 migraines) of telcagepant per month for up to 18 months.
Rizatriptan 10 mg	Participants receive rizatriptan tablets, administered orally as a single dose at onset of migraine. If still experiencing a migraine 2 hours after the first dose of rizatriptan, participants may take an optional second dose of study drug or non-study rescue medication. Participants may take up to 16 doses (for treatment of up to 8 migraines) of rizatriptan per month for up to 18 months.

Measured Values

	Telcagepant 280 mg/300 mg	**Rizatriptan 10 mg**

Number of Participants Analyzed [units: participants]	**592**	**294**
Percentage of Participant Migraine Attacks With Pain Freedom (PF) at 2 Hours Post-Dose [units: Percentage of Migraine Attacks] Mean (Standard Deviation)	**38.9 (29.5)**	**47.5 (29.7)**

Statistical Analysis 1 for Percentage of Participant Migraine Attacks With Pain Freedom (PF) at 2 Hours Post-Dose

Groups [1]	All groups
Odds Ratio (OR) [2]	0.58
95% Confidence Interval	0.45 to 0.75

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant estimation information:
	Based on mixed logistic regression model with a fixed effect term for treatment, baseline pain severity and a random effect term for participant, with the random effect following a normal distribution. An odds ratio >1 is in favor of telcagepant.

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Up to 14 days after any dose of study drug (Up to 18.5 months)
Additional Description	The population consisted of all participants who received at least one dose of study drug.

Reporting Groups

	Description
Telcagepant 280 mg/300 mg	Participants receive telcagepant 300 mg soft gel capsules or telcagepant 280 mg tablets, administered orally as a single dose at onset of migraine. If still experiencing a migraine 2 hours after the first dose of telcagepant, participants may take an optional second dose of study drug or non-study rescue medication. Participants may take up to 16 doses (for treatment of up to 8 migraines) of telcagepant per month for up to 18 months.
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Serious Adverse Events

	Telcagepant 280 mg/300 mg	**Rizatriptan 10 mg**
Total, serious adverse events		
# participants affected / at risk	**12/641 (1.87%)**	**6/313 (1.92%)**
Ear and labyrinth disorders		
Vertigo † 1		

# participants affected / at risk	1/641 (0.16%)	0/313 (0.00%)
Eye disorders		
Cataract † [1]		
# participants affected / at risk	1/641 (0.16%)	0/313 (0.00%)
Gastrointestinal disorders		
Nausea † [1]		
# participants affected / at risk	1/641 (0.16%)	0/313 (0.00%)
General disorders		
Non-cardiac chest pain † [1]		
# participants affected / at risk	0/641 (0.00%)	1/313 (0.32%)
Hepatobiliary disorders		
Cholecystitis † [1]		
# participants affected / at risk	1/641 (0.16%)	0/313 (0.00%)
Infections and infestations		
Appendicitis † [1]		
# participants affected / at risk	1/641 (0.16%)	0/313 (0.00%)
Pneumonia † [1]		
# participants affected / at risk	1/641 (0.16%)	0/313 (0.00%)
Injury, poisoning and procedural complications		
Joint injury † [1]		
# participants affected / at risk	1/641 (0.16%)	0/313 (0.00%)
Wrist fracture † [1]		
# participants affected / at risk	1/641 (0.16%)	0/313 (0.00%)
Musculoskeletal and connective tissue disorders		
Chondromalacia † [1]		
# participants affected / at risk	1/641 (0.16%)	0/313 (0.00%)
Patellofemoral pain syndrome † [1]		
# participants affected / at risk	1/641 (0.16%)	0/313 (0.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Lung neoplasm malignant † [1]		
# participants affected / at risk	1/641 (0.16%)	0/313 (0.00%)
Sqamous cell carcinoma † [1]		
# participants affected / at risk	1/641 (0.16%)	0/313 (0.00%)
Nervous system disorders		
Migraine † [1]		
# participants affected / at risk	0/641 (0.00%)	1/313 (0.32%)
Syncope † [1]		
# participants affected / at risk	0/641 (0.00%)	1/313 (0.32%)
Psychiatric disorders		
Bipolar disorder † [1]		

# participants affected / at risk	**1/641 (0.16%)**	**0/313 (0.00%)**
Renal and urinary disorders		
Nephrolithiasis † 1		
# participants affected / at risk	**0/641 (0.00%)**	**1/313 (0.32%)**
Reproductive system and breast disorders		
Uterovaginal prolapse † 1		
# participants affected / at risk	**1/641 (0.16%)**	**0/313 (0.00%)**
Vaginal prolapse † 1		
# participants affected / at risk	**0/641 (0.00%)**	**1/313 (0.32%)**
Vascular disorders		
Haematoma † 1		
# participants affected / at risk	**0/641 (0.00%)**	**1/313 (0.32%)**

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

Other Adverse Events

Hide Other Adverse Events

Time Frame	Up to 14 days after any dose of study drug (Up to 18.5 months)
Additional Description	The population consisted of all participants who received at least one dose of study drug.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Telcagepant 280 mg/300 mg	Participants receive telcagepant 300 mg soft gel capsules or telcagepant 280 mg tablets, administered orally as a single dose at onset of migraine. If still experiencing a migraine 2 hours after the first dose of telcagepant, participants may take an optional second dose of study drug or non-study rescue medication. Participants may take up to 16 doses (for treatment of up to 8 migraines) of telcagepant per month for up to 18 months.
Rizatriptan 10 mg	Participants receive rizatriptan tablets, administered orally as a single dose at onset of migraine. If still experiencing a migraine 2 hours after the first dose of rizatriptan, participants may take an optional second dose of study drug or non-study rescue medication. Participants may take up to 16 doses (for treatment of up to 8 migraines) of rizatriptan per month for up to 18 months.

Other Adverse Events

	Telcagepant 280 mg/300 mg	**Rizatriptan 10 mg**
Total, other (not including serious) adverse events		
# participants affected / at risk	**187/641 (29.17%)**	**127/313 (40.58%)**
Gastrointestinal disorders		

Dry mouth † 1		
# participants affected / at risk	**62/641 (9.67%)**	**43/313 (13.74%)**
Nausea † 1		
# participants affected / at risk	**58/641 (9.05%)**	**20/313 (6.39%)**
General disorders		
Asthenia † 1		
# participants affected / at risk	**14/641 (2.18%)**	**16/313 (5.11%)**
Fatigue † 1		
# participants affected / at risk	**31/641 (4.84%)**	**32/313 (10.22%)**
Infections and infestations		
Upper respiratory tract infection † 1		
# participants affected / at risk	**17/641 (2.65%)**	**16/313 (5.11%)**
Nervous system disorders		
Dizziness † 1		
# participants affected / at risk	**57/641 (8.89%)**	**32/313 (10.22%)**
Somnolence † 1		
# participants affected / at risk	**59/641 (9.20%)**	**52/313 (16.61%)**

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

Limitations and Caveats

Hide Limitations and Caveats

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

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.

There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

The agreement is:

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

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

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

Restriction Description: The 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 of Results:

Connor KM, Aurora SK, Loeys T, Ashina M, Jones C, Giezek H, Massaad R, Williams-Diaz A, Lines C, Ho TW. Long-term tolerability of telcagepant for acute treatment of migraine in a randomized trial. Headache. 2011 Jan;51(1):73-84. doi: 10.1111/j.1526-4610.2010.01799.x. Epub 2010 Nov 10.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00443209 History of Changes
Other Study ID Numbers:	0974-012 MK-0974-012 (Other Identifier: Merck Protocol Number) 2006_524 (Other Identifier: Telerx Study Number)
Study First Received:	February 28, 2007
Results First Received:	July 29, 2014
Last Updated:	July 13, 2015
Health Authority:	United States: Food and Drug Administration

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