Telcagepant for Prevention of Menstrually Related Migraine in Female Participants With Episodic Migraine (MK-0974-065)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT01125774

First received: May 17, 2010
Last updated: June 30, 2015
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History of Changes

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Purpose

This is a multicenter study to test the hypothesis that telcagepant is superior to placebo in preventing perimenstrual migraines as measured by mean monthly headaches during the entire treatment period. This study will also evaluate the safety and tolerability of telcagepant for female migraine participants.

Condition	Intervention	Phase
Migraine	Drug: Telcagepant Drug: Placebo	Phase 2 Phase 3

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

Official Title: A Six Month Phase II/III, Randomized, Double-Blind, Placebo-Controlled Clinical Trial to Evaluate the Safety, Tolerability, and Efficacy of Telcagepant (MK-0974) for Prevention of Menstrually Related Migraine in Female Patients With Episodic Migraine

Resource links provided by NLM:

MedlinePlus related topics: Headache Migraine

U.S. FDA Resources

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

Primary Outcome Measures:

Number of Participants With Clinical Adverse Events (AEs) [Time Frame: Up to 14 days after the last dose of study drug (Up to 6.5 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 drug, whether or not considered related to the use of the study drug. 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 drug, is also an AE. A clinical AE is an AE reported as a result of a clinical examination or reported by the participant.

- Number of Participants Who Discontinued Study Due to a Clinical AE [Time Frame: Up to 6 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 drug, whether or not considered related to the use of the study drug. 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 drug, is also an AE. A clinical AE is an AE reported as a result of a clinical examination or reported by the participant.

- Number of Participants With Laboratory AEs [Time Frame: Up to 6 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 drug, whether or not considered related to the use of the study drug. 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 drug, is also an AE. A laboratory AE is an AE reported as a result of a laboratory assessment or test.

- Number of Participants Who Discontinued Study Due to a Laboratory AE [Time Frame: Up to 6 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 drug, whether or not considered related to the use of the study drug. 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 drug, is also an AE. A laboratory AE is an AE reported as a result of a laboratory assessment or test.

- Mean Monthly Headache Days During Entire Study Period Among Participants With Menstrually-related Migraine (MRM) or Pure Menstrual Migraine (PMM) Who Have an Average of 5 or More Moderate or Severe Migraine Headaches Per Month at Baseline [Time Frame: Up to 6 months] [Designated as safety issue: No]

  Participants completed a headache diary each evening at bedtime, including recording headache duration and acute headache medication use. Mean monthly headache days was calculated from diary data. A headache day was defined as a day in which a headache (defined as headache pain ≥30 minute duration or requiring acute treatment) started, ended, or recurred. Headache pain persisting for more than 1 calendar day after initial onset was considered an occurrence of additional headache days. Mean monthly rate was adjusted to 28 days. Participant subgroups (based on symptoms over the 3 menstrual cycles prior to study): PMM - In ≥2 out of 3 cycles attacks occur exclusively on Day 1 ± 2 of menstruation and at no other times of the cycle; MRM - In ≥2 out of 3 cycles attacks occur on Day 1 ± 2 of menstruation and additionally at other times of the cycle.

Secondary Outcome Measures:

- Mean Monthly Headache Days During Entire Study Period Among Participants With MRM Who Have an Average of 5 or More Moderate or Severe Migraine Headaches Per Month at Baseline [Time Frame: Up to 6 months] [Designated as safety issue: No]

  Participants completed a headache diary each evening at bedtime, including recording headache duration and acute headache medication use. Mean monthly headache days was calculated from diary data. A headache day was defined as a day in which a headache (defined as headache pain ≥30 minute duration or requiring acute treatment) started, ended, or recurred. Headache pain persisting for more than 1 calendar day after initial onset was considered an occurrence of additional headache days. Mean monthly rate was adjusted to 28 days. MRM participant subgroup (based on symptoms over the 3 menstrual cycles prior to study) - In ≥2 out of 3 cycles attacks occur on Day 1 ± 2 of menstruation and additionally at other times of the cycle.

- Mean Monthly On-drug Headache Days During the Entire Study Period Among Participants With MRM or PMM Who Have an Average of 5 or More Moderate or Severe Migraine Headaches Per Month at Baseline [Time Frame: Up to 6 months] [Designated as safety issue: No]

  Participants completed a headache diary each evening at bedtime, including recording headache duration and acute headache medication use. Mean monthly on-drug headache days was calculated from diary data. "On-drug" headache day was a day, which had a valid diary entry and which followed a study drug dosing day, in which a headache (defined as headache pain ≥30 minute duration or requiring acute treatment) started, ended, or recurred. Headache pain persisting for more than 1 calendar day after initial onset into additional qualifying days (i.e., day following dosing day) was considered an occurrence of additional headache days. Mean monthly rate was adjusted to 7 days. Participant subgroups (based on symptoms over the 3 menstrual cycles prior to study): PMM - In ≥2 out of 3 cycles attacks occur exclusively on Day 1 ± 2 of menstruation and at no other times of the cycle; MRM - In ≥2 out of 3 cycles attacks occur on Day 1 ± 2 of menstruation and additionally at other times of the cycle.

- Mean Monthly On-drug Headache Days During the Entire Study Period Among Participants With MRM Who Have an Average of 5 or More Moderate or Severe Migraine Headaches Per Month at Baseline [Time Frame: Up to 6 months] [Designated as safety issue: No]

  Participants completed a headache diary each evening at bedtime, including recording headache duration and acute headache medication use. Mean monthly on-drug headache days was calculated from diary data. "On-drug" headache day was a day, which had a valid diary entry and which followed a study drug dosing day, in which a headache (defined as headache pain ≥30 minute duration or requiring acute treatment) started, ended, or recurred. Headache pain persisting for more than 1 calendar day after initial onset into additional qualifying days (i.e., day following dosing day) was considered an occurrence of additional headache days. Mean monthly rate was adjusted to 7 days. MRM participant subgroup (based on symptoms over the 3 menstrual cycles prior to study) - In ≥2 out of 3 cycles attacks occur on Day 1 ± 2 of menstruation additionally at other times of the cycle.

- Mean Monthly On-drug Headache Days During the Entire Study Period Among Participants With PMM Who Have an Average of 3 or More Moderate or Severe Migraine Headaches Per Month at Baseline [Time Frame: Up to 6 months] [Designated as safety issue: No]

  Participants completed a headache diary each evening at bedtime, including recording headache duration and acute headache medication use. Mean monthly on-drug headache days was calculated from diary data. "On-drug" headache day was a day, which had a valid diary entry and which followed a study drug dosing day, in which a headache (defined as headache pain ≥30 minute duration or requiring acute treatment) started, ended, or recurred. Headache pain persisting for more than 1 calendar day after initial onset into additional qualifying days (i.e., day following dosing day) was considered an occurrence of additional headache days. Mean monthly rate was adjusted to 7 days. PMM participant subgroups (based on symptoms over the 3 menstrual cycles prior to study) - In ≥2 out of 3 cycles attacks occur exclusively on Day 1 ± 2 of menstruation and at no other times of the cycle.

Enrollment:	4548
Study Start Date:	June 2010
Study Completion Date:	April 2011
Primary Completion Date:	April 2011 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Telcagepant Telcagepant 140 mg was administered once daily at bedtime for 7 consecutive days each month, beginning at the onset of menses, for up to 6 months. Dosing could begin up to 3 days prior to menses onset if prodromal symptoms reliably predicted onset of menses.	Drug: Telcagepant Telcagepant 140 mg film coated tablet for oral administration Other Name: MK-0974
Placebo Comparator: Placebo Placebo was administered once daily at bedtime for 7 consecutive days each month, beginning at the onset of menses, for up to 6 months. Dosing could begin up to 3 days prior to menses onset if prodromal symptoms reliably predicted onset of menses.	Drug: Placebo Placebo to match telcagepant 140 mg film coated tablet for oral administration

Eligibility

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

Criteria

Inclusion Criteria:

- Participant who has had regular menstrual cycles monthly (22 to 32 days) for at least the last 3 cycles
- Participant experiences headache during menstrual period in at least 2 out of last 3 cycles
- Participant has history of migraine for ≥ 3 months and with ≥ 2 migraine attacks per month in the 2 months prior to screening
- Participant agrees to use an effective method of birth control through the duration of the study

Exclusion Criteria:

- Participant has basilar or hemiplegic migraine headache
- Participant has taken medication for acute headache on more than 15 days per month in the 3 months prior to screening
- Participant is taking prophylactic medication for migraine and daily dose has changed within 4 weeks prior to screening
- Participant has history of significant liver disease

- Participant has had cardiac surgery or symptoms within 3 months of screening
- Participant has confounding pain syndromes, psychiatric conditions, dementia, or major neurological disorders other than migraine
- Participant has history of neoplastic disease ≤ 5 years prior to signing informed consent
- Participant has history of gastric or small intestinal surgery
- Participant consumes 3 or more alcoholic drinks per day

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: NCT01125774

Sponsors and Collaborators

Merck Sharp & Dohme Corp.

Investigators

Study Director: Medical Director Merck Sharp & Dohme Corp.

More Information

Publications:

Ho TW, Ho AP, Ge YJ, Assaid C, Gottwald R, MacGregor EA, Mannix LK, van Oosterhout WP, Koppenhaver J, Lines C, Ferrari MD, Michelson D. Randomized controlled trial of the CGRP receptor antagonist telcagepant for prevention of headache in women with perimenstrual migraine. Cephalalgia. 2016 Feb;36(2):148-61. doi: 10.1177/0333102415584308. Epub 2015 Apr 29.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT01125774 History of Changes
Other Study ID Numbers:	0974-065 2010_535
Study First Received:	May 17, 2010
Results First Received:	October 1, 2014
Last Updated:	June 30, 2015
Health Authority:	United States: Food and Drug Administration

Keywords provided by Merck Sharp & Dohme Corp.:
Menstrually related migraine
migraine
Premenstrual migraine

Additional relevant MeSH terms:

Migraine Disorders	Headache Disorders
Brain Diseases	Headache Disorders, Primary
Central Nervous System Diseases	Nervous System Diseases

ClinicalTrials.gov processed this record on May 08, 2016

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Results First Received: October 1, 2014

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator, Outcomes Assessor); Primary Purpose: Treatment
Condition:	Migraine
Interventions:	Drug: Telcagepant Drug: Placebo

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
No text entered.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
Participants were randomized to telcagepant 140 mg or placebo. Protocol deviation occurred in which 28 participants (called "duplicate participants") were randomized at more than 1 study site (22 unique participants randomized in total 37 times to telcagepant and 12 times to placebo; 6 unique participants randomized in total 12 times to placebo)

Reporting Groups

	Description
Telcagepant 140 mg - Excluding Duplicate Participants	Participants who were randomized at only 1 study site and were randomized to telcagepant. Telcagepant 140 mg was administered once daily at bedtime for 7 consecutive days each month, beginning at the onset of menses, for up to 6 months. Dosing could begin up to 3 days prior to menses onset if prodromal symptoms reliably predicted onset of menses.
Placebo - Excluding Duplicate Participants	Participants who were randomized at only 1 study site and were randomized to placebo. Placebo was administered once daily at bedtime for 7 consecutive days each month, beginning at the onset of menses, for up to 6 months. Dosing could begin up to 3 days prior to menses onset if prodromal symptoms reliably predicted onset of menses.
Telcagepant 140 mg - Duplicate Participants	Participants who were randomized at more than 1 study site and were randomized at least once to telcagepant and may also have been randomized to placebo. Study drug was administered once daily at bedtime for 7 consecutive days each month, beginning at the onset of menses, for up to 6 months. Dosing could begin up to 3 days prior to menses onset if prodromal symptoms reliably predicted onset of menses.
Placebo - Duplicate Participants	Participants who were randomized at more than 1 study site and each time were randomized to placebo. Placebo was administered once daily at bedtime for 7 consecutive days each month, beginning at the onset of menses, for up to 6 months. Dosing could begin up to 3 days prior to menses onset if prodromal symptoms reliably predicted onset of menses.

Participant Flow: Overall Study

	Telcagepant 140 mg - Excluding Duplicate Participants	Placebo - Excluding Duplicate Participants	Telcagepant 140 mg - Duplicate Participants	Placebo - Duplicate Participants
STARTED	3018 [1]	1502 [1]	22 [2]	6 [2]
Treated	2638	1322 [3]	21 [4]	5
COMPLETED	1893	948	13 [5]	3 [6]
NOT COMPLETED	1125	554	9	3

[1] Randomized
[2] Unique participants randomized
[3] 1 mistakenly took telcagepant and is included with telcagepant group for adverse event analysis
[4] Received telcagepant
[5] Completed study at least once while treated with telcagepant (otherwise counted "Not Completed")
[6] Completed study at least once

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All randomized participants, including those randomized at more than 1 site ("duplicate participants"). Participants randomized at more than 1 site resulting in randomization into both telcagepant 140 mg and placebo groups are allocated to the telcagepant 140 mg group.

Reporting Groups

	Description
Telcagepant 140 mg	Telcagepant 140 mg was administered once daily at bedtime for 7 consecutive days each month, beginning at the onset of menses, for up to 6 months. Dosing could begin up to 3 days prior to menses onset if prodromal symptoms reliably predicted onset of menses.
Placebo	Placebo was administered once daily at bedtime for 7 consecutive days each month, beginning at the onset of menses, for up to 6 months. Dosing could begin up to 3 days prior to menses onset if prodromal symptoms reliably predicted onset of menses.
Total	Total of all reporting groups

Baseline Measures

	Telcagepant 140 mg	Placebo	Total
Number of Participants [units: participants]	**3040**	**1508**	**4548**
Age [1] [units: Years] Mean (Standard Deviation)	**36.1 (8.6)**	**35.8 (8.7)**	**36.0 (8.6)**
Gender [units: Participants]			
Female	**3040**	**1508**	**4548**
Male	**0**	**0**	**0**

[1] Due to missing data, N=3039 and 4547 for Telcagepant 140 mg and Total groups, respectively.

Outcome Measures

Hide All Outcome Measures

1. Primary: Number of Participants With Clinical Adverse Events (AEs) [Time Frame: Up to 14 days after the last dose of study drug (Up to 6.5 months)]

Measure Type	Primary
Measure Title	Number of Participants With Clinical Adverse Events (AEs)
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 study drug. 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 drug, is also an AE. A clinical AE is an AE reported as a result of a clinical examination or reported by the participant.
Time Frame	Up to 14 days after the last dose of study drug (Up to 6.5 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.
All Participants as Treated (APaT) population, which included all randomized participants who took at least one dose of study drug. Participants were included in the treatment arm corresponding to the study treatment actually taken. Participants who took both study treatments were included in the telcagepant 140 mg treatment arm.

Reporting Groups

	Description
Telcagepant 140 mg	Telcagepant 140 mg was administered once daily at bedtime for 7 consecutive days each month, beginning at the onset of menses, for up to 6 months. Dosing could begin up to 3 days prior to menses onset if prodromal symptoms reliably predicted onset of menses.
Placebo	Placebo was administered once daily at bedtime for 7 consecutive days each month, beginning at the onset of menses, for up to 6 months. Dosing could begin up to 3 days prior to menses onset if prodromal symptoms reliably predicted onset of menses.

Measured Values

	Telcagepant 140 mg	Placebo
Number of Participants Analyzed [units: participants]	**2660**	**1326**
Number of Participants With Clinical Adverse Events (AEs) [units: Participants]	**1582**	**804**

Statistical Analysis 1 for Number of Participants With Clinical Adverse Events (AEs)

Groups [1]	All groups
Method [2]	Miettinen & Nurminen
Difference in percent incidence [3]	-1.2
95% Confidence Interval	-4.4 to 2.1

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Other relevant estimation information:
	Telcagepant percent incidence versus Placebo percent incidence

2. Primary: Number of Participants Who Discontinued Study Due to a Clinical AE [Time Frame: Up to 6 months]

Measure Type	Primary
Measure Title	Number of Participants Who Discontinued Study Due to a 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 drug, whether or not considered related to the use of the study drug. 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 drug, is also an AE. A clinical AE is an AE reported as a result of a clinical examination or reported by the participant.
Time Frame	Up to 6 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.
APaT population, which included all randomized participants who took at least one dose of study drug. Participants were included in the treatment arm corresponding to the study treatment actually taken. Participants who took both study treatments were included in the telcagepant 140 mg treatment arm.

Reporting Groups

	Description
Telcagepant 140 mg	Telcagepant 140 mg was administered once daily at bedtime for 7 consecutive days each month, beginning at the onset of menses, for up to 6 months. Dosing could begin up to 3 days prior to menses onset if prodromal symptoms reliably predicted onset of menses.
Placebo	Placebo was administered once daily at bedtime for 7 consecutive days each month, beginning at the onset of menses, for up to 6 months. Dosing could begin up to 3 days prior to menses onset if prodromal symptoms reliably predicted onset of menses.

Measured Values

	Telcagepant 140 mg	**Placebo**
Number of Participants Analyzed [units: participants]	**2660**	**1326**
Number of Participants Who Discontinued Study Due to a Clinical AE [units: Participants]	**66**	**36**

Statistical Analysis 1 for Number of Participants Who Discontinued Study Due to a Clinical AE

Groups [1]	All groups
Method [2]	Miettinen & Nurminen
Difference in percent incidence [3]	-0.2
95% Confidence Interval	-1.4 to 0.8

[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]	Other relevant estimation information:
	Telcagepant percent incidence versus Placebo percent incidence

3. Primary: Number of Participants With Laboratory AEs [Time Frame: Up to 6 months]

Measure Type	Primary
Measure Title	Number of Participants With Laboratory AEs
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 study drug. 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 drug, is also an AE. A laboratory AE is an AE reported as a result of a laboratory assessment or test.
Time Frame	Up to 6 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.
APaT population, which is all randomized participants who took at least one dose of study drug. Also to be included participant must have at least one post-baseline lab test. Participants were included in arm corresponding to the treatment actually taken. Participants who took both treatments were included in the telcagepant 140 mg treatment arm.

Reporting Groups

	Description
Telcagepant 140 mg	Telcagepant 140 mg was administered once daily at bedtime for 7 consecutive days each month, beginning at the onset of menses, for up to 6 months. Dosing could begin up to 3 days prior to menses onset if prodromal symptoms reliably predicted onset of menses.
Placebo	Placebo was administered once daily at bedtime for 7 consecutive days each month, beginning at the onset of menses, for up to 6 months. Dosing could begin up to 3 days prior to menses onset if prodromal symptoms reliably predicted onset of menses.

Measured Values

	Telcagepant 140 mg	**Placebo**
Number of Participants Analyzed [units: participants]	**2610**	**1305**
Number of Participants With Laboratory AEs [units: Participants]	**76**	**30**

Statistical Analysis 1 for Number of Participants With Laboratory AEs

Groups [1]	All groups
Method [2]	Miettinen & Nurminen
Difference in percent incidence [3]	0.6
95% Confidence Interval	-0.5 to 1.6

[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]	Other relevant estimation information:
	Telcagepant percent incidence versus Placebo percent incidence

4. Primary: Number of Participants Who Discontinued Study Due to a Laboratory AE [Time Frame: Up to 6 months]

Measure Type	Primary
Measure Title	Number of Participants Who Discontinued Study Due to a 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 drug, whether or not considered related to the use of the study drug. 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 drug, is also an AE. A laboratory AE is an AE reported as a result of a laboratory assessment or test.
Time Frame	Up to 6 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.
APaT population, which is all randomized participants who took at least one dose of study drug. Also to be included participant must have at least one post-baseline lab test. Participants were included in arm corresponding to the treatment actually taken. Participants who took both treatments were included in the telcagepant 140 mg treatment arm.

Reporting Groups

	Description
Telcagepant 140 mg	Telcagepant 140 mg was administered once daily at bedtime for 7 consecutive days each month, beginning at the onset of menses, for up to 6 months. Dosing could begin up to 3 days prior to menses onset if prodromal symptoms reliably predicted onset of menses.
Placebo	Placebo was administered once daily at bedtime for 7 consecutive days each month, beginning at the onset of menses, for up to 6 months. Dosing could begin up to 3 days prior to menses onset if prodromal symptoms reliably predicted onset of menses.

Measured Values

	Telcagepant 140 mg	**Placebo**
Number of Participants Analyzed [units: participants]	**2610**	**1305**
Number of Participants Who Discontinued Study Due to a Laboratory AE [units: Participants]	**8**	**2**

No statistical analysis provided for Number of Participants Who Discontinued Study Due to a Laboratory AE

5. Primary: Mean Monthly Headache Days During Entire Study Period Among Participants With Menstrually-related Migraine (MRM) or Pure Menstrual Migraine (PMM) Who Have an Average of 5 or More Moderate or Severe Migraine Headaches Per Month at Baseline [Time Frame: Up to 6 months]

Measure Type	Primary
Measure Title	Mean Monthly Headache Days During Entire Study Period Among Participants With Menstrually-related Migraine (MRM) or Pure Menstrual Migraine (PMM) Who Have an Average of 5 or More Moderate or Severe Migraine Headaches Per Month at Baseline

Measure Description	Participants completed a headache diary each evening at bedtime, including recording headache duration and acute headache medication use. Mean monthly headache days was calculated from diary data. A headache day was defined as a day in which a headache (defined as headache pain ≥30 minute duration or requiring acute treatment) started, ended, or recurred. Headache pain persisting for more than 1 calendar day after initial onset was considered an occurrence of additional headache days. Mean monthly rate was adjusted to 28 days. Participant subgroups (based on symptoms over the 3 menstrual cycles prior to study): PMM – In ≥2 out of 3 cycles attacks occur exclusively on Day 1 ± 2 of menstruation and at no other times of the cycle; MRM - In ≥2 out of 3 cycles attacks occur on Day 1 ± 2 of menstruation and additionally at other times of the cycle.
Time Frame	Up to 6 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.
All randomized participants who were randomized only once, took at least 1 dose of study drug, had ≥1 post-randomization efficacy measurement, met the definition of the MRM or PMM subgroup and reported average of ≥5 moderate-severe migraine headaches/month at baseline. Participant must have ≥1 month with ≥4 dosing days and ≥7 diary days.

Reporting Groups

	Description
Telcagepant 140 mg	Telcagepant 140 mg was administered once daily at bedtime for 7 consecutive days each month, beginning at the onset of menses, for up to 6 months. Dosing could begin up to 3 days prior to menses onset if prodromal symptoms reliably predicted onset of menses.
Placebo	Placebo was administered once daily at bedtime for 7 consecutive days each month, beginning at the onset of menses, for up to 6 months. Dosing could begin up to 3 days prior to menses onset if prodromal symptoms reliably predicted onset of menses.

Measured Values

	Telcagepant 140 mg	**Placebo**
Number of Participants Analyzed [units: participants]	**887**	**447**
Mean Monthly Headache Days During Entire Study Period Among Participants With Menstrually-related Migraine (MRM) or Pure Menstrual Migraine (PMM) Who Have an Average of 5 or More Moderate or Severe Migraine Headaches Per Month at Baseline [units: Days per month] Mean (Standard Error)	**8.8 (0.19)**	**9.3 (0.26)**

Statistical Analysis 1 for Mean Monthly Headache Days During Entire Study Period Among Participants With Menstrually-related Migraine (MRM) or Pure Menstrual Migraine (PMM) Who Have an Average of 5 or More Moderate or Severe Migraine Headaches Per Month at Baseline

Groups [1]	All groups
Method [2]	Longitudinal data analysis (LDA)
P Value [3]	0.130
Mean Difference (Final Values) [4]	-0.5
95% Confidence Interval	-1.1 to 0.1

[1]	Additional details about the analysis, such as null hypothesis and power calculation:

	This measure tests the primary hypothesis, that telcagepant 140 mg is superior to placebo as measured by mean monthly headache days in participants with MRM or PMM
[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:
	α=0.0499
[4]	Other relevant estimation information:
	Difference is Telcagepant 140 mg versus Placebo

6. Secondary: Mean Monthly Headache Days During Entire Study Period Among Participants With MRM Who Have an Average of 5 or More Moderate or Severe Migraine Headaches Per Month at Baseline [Time Frame: Up to 6 months]

Measure Type	Secondary
Measure Title	Mean Monthly Headache Days During Entire Study Period Among Participants With MRM Who Have an Average of 5 or More Moderate or Severe Migraine Headaches Per Month at Baseline
Measure Description	Participants completed a headache diary each evening at bedtime, including recording headache duration and acute headache medication use. Mean monthly headache days was calculated from diary data. A headache day was defined as a day in which a headache (defined as headache pain ≥30 minute duration or requiring acute treatment) started, ended, or recurred. Headache pain persisting for more than 1 calendar day after initial onset was considered an occurrence of additional headache days. Mean monthly rate was adjusted to 28 days. MRM participant subgroup (based on symptoms over the 3 menstrual cycles prior to study) - In ≥2 out of 3 cycles attacks occur on Day 1 ± 2 of menstruation and additionally at other times of the cycle.
Time Frame	Up to 6 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.
All randomized participants who were randomized only once, took at least 1 dose of study drug, had ≥1 post-randomization efficacy measurement, met the definition of the MRM subgroup and reported average of ≥5 moderate-severe migraine headaches/month at baseline. Participant must have ≥1 month with ≥4 dosing days and ≥7 diary days.

Reporting Groups

	Description
Telcagepant 140 mg	Telcagepant 140 mg was administered once daily at bedtime for 7 consecutive days each month, beginning at the onset of menses, for up to 6 months. Dosing could begin up to 3 days prior to menses onset if prodromal symptoms reliably predicted onset of menses.
Placebo	Placebo was administered once daily at bedtime for 7 consecutive days each month, beginning at the onset of menses, for up to 6 months. Dosing could begin up to 3 days prior to menses onset if prodromal symptoms reliably predicted onset of menses.

Measured Values

	Telcagepant 140 mg	**Placebo**

Number of Participants Analyzed [units: participants]	**731**	**382**
Mean Monthly Headache Days During Entire Study Period Among Participants With MRM Who Have an Average of 5 or More Moderate or Severe Migraine Headaches Per Month at Baseline [units: Days per month] Mean (Standard Error)	**9.3 (0.20)**	**9.6 (0.28)**

Statistical Analysis 1 for Mean Monthly Headache Days During Entire Study Period Among Participants With MRM Who Have an Average of 5 or More Moderate or Severe Migraine Headaches Per Month at Baseline

Groups [1]	All groups
Method [2]	LDA
P Value [3]	0.369
Mean Difference (Final Values) [4]	-0.3
95% Confidence Interval	-1.0 to 0.4

[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:
	To control Type I error, formal significance of the test for treatment difference for this measure could only be achieved if the comparison corresponding to the primary hypothesis was significant at α=0.0499
[4]	Other relevant estimation information:
	Difference is Telcagepant 140 mg versus Placebo

7. Secondary: Mean Monthly On-drug Headache Days During the Entire Study Period Among Participants With MRM or PMM Who Have an Average of 5 or More Moderate or Severe Migraine Headaches Per Month at Baseline [Time Frame: Up to 6 months]

Measure Type	Secondary
Measure Title	Mean Monthly On-drug Headache Days During the Entire Study Period Among Participants With MRM or PMM Who Have an Average of 5 or More Moderate or Severe Migraine Headaches Per Month at Baseline
Measure Description	Participants completed a headache diary each evening at bedtime, including recording headache duration and acute headache medication use. Mean monthly on-drug headache days was calculated from diary data. “On-drug” headache day was a day, which had a valid diary entry and which followed a study drug dosing day, in which a headache (defined as headache pain ≥30 minute duration or requiring acute treatment) started, ended, or recurred. Headache pain persisting for more than 1 calendar day after initial onset into additional qualifying days (i.e., day following dosing day) was considered an occurrence of additional headache days. Mean monthly rate was adjusted to 7 days. Participant subgroups (based on symptoms over the 3 menstrual cycles prior to study): PMM – In ≥2 out of 3 cycles attacks occur exclusively on Day 1 ± 2 of menstruation and at no other times of the cycle; MRM - In ≥2 out of 3 cycles attacks occur on Day 1 ± 2 of menstruation and additionally at other times of the cycle.
Time Frame	Up to 6 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.
All randomized participants who were randomized only once, took at least 1 dose of study drug, had ≥1 post-randomization efficacy measurement, met the definition of the MRM or PMM subgroup and reported average of ≥5 moderate-severe migraine headaches/month at baseline. Participant must have ≥1 month with ≥4 dosing days.

Reporting Groups

	Description
Telcagepant 140 mg	Telcagepant 140 mg was administered once daily at bedtime for 7 consecutive days each month, beginning at the onset of menses, for up to 6 months. Dosing could begin up to 3 days prior to menses onset if prodromal symptoms reliably predicted onset of menses.
Placebo	Placebo was administered once daily at bedtime for 7 consecutive days each month, beginning at the onset of menses, for up to 6 months. Dosing could begin up to 3 days prior to menses onset if prodromal symptoms reliably predicted onset of menses.

Measured Values

	Telcagepant 140 mg	**Placebo**
Number of Participants Analyzed [units: participants]	**887**	**448**
Mean Monthly On-drug Headache Days During the Entire Study Period Among Participants With MRM or PMM Who Have an Average of 5 or More Moderate or Severe Migraine Headaches Per Month at Baseline [units: Days per month] Mean (Standard Error)	**2.5 (0.05)**	**2.9 (0.08)**

Statistical Analysis 1 for Mean Monthly On-drug Headache Days During the Entire Study Period Among Participants With MRM or PMM Who Have an Average of 5 or More Moderate or Severe Migraine Headaches Per Month at Baseline

Groups [1]	All groups
Method [2]	LDA
P Value [3]	<0.001
Mean Difference (Final Values) [4]	-0.4
95% Confidence Interval	-0.5 to -0.2

[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:
	To control Type I error, formal significance of the test for treatment difference for this measure could only be achieved if the comparison corresponding to the primary hypothesis was significant at α=0.0499
[4]	Other relevant estimation information:
	Difference is Telcagepant 140 mg versus Placebo

8. Secondary: Mean Monthly On-drug Headache Days During the Entire Study Period Among Participants With MRM Who Have an Average of 5 or More Moderate or Severe Migraine Headaches Per Month at Baseline [Time Frame: Up to 6 months]

Measure Type	Secondary
Measure Title	Mean Monthly On-drug Headache Days During the Entire Study Period Among Participants With MRM Who Have an Average of 5 or More Moderate or Severe Migraine Headaches Per Month at Baseline
Measure Description	Participants completed a headache diary each evening at bedtime, including recording headache duration and acute headache medication use. Mean monthly on-drug headache days was calculated from diary data. “On-drug” headache day was a day, which had a valid diary entry and which followed a study drug dosing day, in which a headache (defined as headache pain ≥30 minute duration or requiring acute treatment) started, ended, or recurred. Headache pain persisting for more than 1 calendar day after initial onset into additional qualifying days (i.e., day following dosing day) was considered an occurrence of additional headache days. Mean monthly rate was adjusted to 7 days. MRM participant subgroup (based on symptoms over the 3 menstrual cycles prior to study) - In ≥2 out of 3 cycles attacks occur on Day 1 ± 2 of menstruation additionally at other times of the cycle.
Time Frame	Up to 6 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.
All randomized participants who were randomized only once, took at least 1 dose of study drug, had ≥1 post-randomization efficacy measurement, met the definition of the MRM subgroup and reported average of ≥5 moderate-severe migraine headaches/month at baseline. Participant must have ≥1 month with ≥4 dosing days.

Reporting Groups

	Description
Telcagepant 140 mg	Telcagepant 140 mg was administered once daily at bedtime for 7 consecutive days each month, beginning at the onset of menses, for up to 6 months. Dosing could begin up to 3 days prior to menses onset if prodromal symptoms reliably predicted onset of menses.
Placebo	Placebo was administered once daily at bedtime for 7 consecutive days each month, beginning at the onset of menses, for up to 6 months. Dosing could begin up to 3 days prior to menses onset if prodromal symptoms reliably predicted onset of menses.

Measured Values

	Telcagepant 140 mg	**Placebo**
Number of Participants Analyzed [units: participants]	**731**	**383**
Mean Monthly On-drug Headache Days During the Entire Study Period Among Participants With MRM Who Have an Average of 5 or More Moderate or Severe Migraine Headaches Per Month at Baseline [units: Days per month] Mean (Standard Error)	**2.6 (0.06)**	**3.0 (0.08)**

Statistical Analysis 1 for Mean Monthly On-drug Headache Days During the Entire Study Period Among Participants With MRM Who Have an Average of 5 or More Moderate or Severe Migraine Headaches Per Month at Baseline

Groups [1]	All groups

Method [2]	LDA
P Value [3]	<0.001
Mean Difference (Final Values) [4]	-0.3
95% Confidence Interval	-0.5 to -0.2

[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:
	To control Type I error, formal significance of the test for treatment difference for this measure could only be achieved if the comparison corresponding to the primary hypothesis was significant at α=0.0499
[4]	Other relevant estimation information:
	Difference is Telcagepant 140 mg versus Placebo

9. Secondary: Mean Monthly On-drug Headache Days During the Entire Study Period Among Participants With PMM Who Have an Average of 3 or More Moderate or Severe Migraine Headaches Per Month at Baseline [Time Frame: Up to 6 months]

Measure Type	Secondary
Measure Title	Mean Monthly On-drug Headache Days During the Entire Study Period Among Participants With PMM Who Have an Average of 3 or More Moderate or Severe Migraine Headaches Per Month at Baseline
Measure Description	Participants completed a headache diary each evening at bedtime, including recording headache duration and acute headache medication use. Mean monthly on-drug headache days was calculated from diary data. “On-drug” headache day was a day, which had a valid diary entry and which followed a study drug dosing day, in which a headache (defined as headache pain ≥30 minute duration or requiring acute treatment) started, ended, or recurred. Headache pain persisting for more than 1 calendar day after initial onset into additional qualifying days (i.e., day following dosing day) was considered an occurrence of additional headache days. Mean monthly rate was adjusted to 7 days. PMM participant subgroups (based on symptoms over the 3 menstrual cycles prior to study) – In ≥2 out of 3 cycles attacks occur exclusively on Day 1 ± 2 of menstruation and at no other times of the cycle.
Time Frame	Up to 6 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.
All randomized participants who were randomized only once, took at least 1 dose of study drug, had ≥1 post-randomization efficacy measurement, met the definition of the PMM subgroup and reported average of ≥3 moderate-severe migraine headaches/month at baseline. Participant must have ≥1 month with ≥4 dosing days.

Reporting Groups

	Description
Telcagepant 140 mg	Telcagepant 140 mg was administered once daily at bedtime for 7 consecutive days each month, beginning at the onset of menses, for up to 6 months. Dosing could begin up to 3 days prior to menses onset if prodromal symptoms reliably predicted onset of menses.

Placebo	Placebo was administered once daily at bedtime for 7 consecutive days each month, beginning at the onset of menses, for up to 6 months. Dosing could begin up to 3 days prior to menses onset if prodromal symptoms reliably predicted onset of menses.

Measured Values

	Telcagepant 140 mg	Placebo
Number of Participants Analyzed [units: participants]	**344**	**151**
Mean Monthly On-drug Headache Days During the Entire Study Period Among Participants With PMM Who Have an Average of 3 or More Moderate or Severe Migraine Headaches Per Month at Baseline [units: Days per month] Mean (Standard Error)	**2.1 (0.08)**	**2.2 (0.12)**

Statistical Analysis 1 for Mean Monthly On-drug Headache Days During the Entire Study Period Among Participants With PMM Who Have an Average of 3 or More Moderate or Severe Migraine Headaches Per Month at Baseline

Groups [1]	All groups
Method [2]	LDA
P Value [3]	0.393
Mean Difference (Final Values) [4]	-0.1
95% Confidence Interval	-0.4 to 0.2

[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:
	To control Type I error, formal significance of the test for treatment difference for this measure could only be achieved if the comparison corresponding to the primary hypothesis was significant at α=0.0499
[4]	Other relevant estimation information:
	Difference is Telcagepant 140 mg versus Placebo

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Up to 14 days after the last dose of study drug (Up to 6.5 months)
Additional Description	APaT population, which included all randomized participants who took at least 1 dose of study drug. Participants were included in the treatment arm corresponding to the study treatment actually taken. Participants who took both study treatments were included in the telcagepant 140 mg treatment arm. Presentation includes clinical and laboratory AEs.

Reporting Groups

	Description
Telcagepant 140 mg	Telcagepant 140 mg was administered once daily at bedtime for 7 consecutive days each month, beginning at the onset of menses, for up to 6 months. Dosing could begin up to 3 days prior to menses onset if prodromal symptoms reliably predicted onset of menses.
Placebo	Placebo was administered once daily at bedtime for 7 consecutive days each month, beginning at the onset of menses, for up to 6 months. Dosing could begin up to 3 days prior to menses onset if prodromal symptoms reliably predicted onset of menses.

Serious Adverse Events

	Telcagepant 140 mg	Placebo
Total, serious adverse events		
# participants affected / at risk	**25/2660 (0.94%)**	**10/1326 (0.75%)**
Cardiac disorders		
Cardiac arrest † 1		
# participants affected / at risk	**1/2660 (0.04%)**	**0/1326 (0.00%)**
# events	**2**	**0**
Myocardial infarction † 1		
# participants affected / at risk	**1/2660 (0.04%)**	**0/1326 (0.00%)**
# events	**1**	**0**
Gastrointestinal disorders		
Pancreatitis † 1		
# participants affected / at risk	**2/2660 (0.08%)**	**0/1326 (0.00%)**
# events	**2**	**0**
Peptic ulcer haemorrhage † 1		
# participants affected / at risk	**0/2660 (0.00%)**	**1/1326 (0.08%)**
# events	**0**	**1**
General disorders		
Chest pain † 1		
# participants affected / at risk	**1/2660 (0.04%)**	**0/1326 (0.00%)**
# events	**1**	**0**
Hepatobiliary disorders		
Cholelithiasis obstructive † 1		
# participants affected / at risk	**1/2660 (0.04%)**	**0/1326 (0.00%)**
# events	**1**	**0**
Immune system disorders		
Anaphylactic reaction † 1		
# participants affected / at risk	**1/2660 (0.04%)**	**0/1326 (0.00%)**
# events	**1**	**0**
Hypersensitivity † 1		
# participants affected / at risk	**1/2660 (0.04%)**	**0/1326 (0.00%)**
# events	**1**	**0**
Infections and infestations		

Cellulitis † 1		
# participants affected / at risk	**1/2660 (0.04%)**	**0/1326 (0.00%)**
# events	**1**	**0**
Cervicitis † 1		
# participants affected / at risk	**1/2660 (0.04%)**	**0/1326 (0.00%)**
# events	**1**	**0**
Injury, poisoning and procedural complications		
Comminuted fracture † 1		
# participants affected / at risk	**0/2660 (0.00%)**	**1/1326 (0.08%)**
# events	**0**	**1**
Contusion † 1		
# participants affected / at risk	**1/2660 (0.04%)**	**0/1326 (0.00%)**
# events	**1**	**0**
Post procedural haemorrhage † 1		
# participants affected / at risk	**1/2660 (0.04%)**	**0/1326 (0.00%)**
# events	**1**	**0**
Traumatic brain injury † 1		
# participants affected / at risk	**0/2660 (0.00%)**	**1/1326 (0.08%)**
# events	**0**	**1**
Investigations		
Alanine aminotransferase increased † 1		
# participants affected / at risk	**3/2660 (0.11%)**	**0/1326 (0.00%)**
# events	**3**	**0**
Aspartate aminotransferase increased † 1		
# participants affected / at risk	**1/2660 (0.04%)**	**0/1326 (0.00%)**
# events	**1**	**0**
Metabolism and nutrition disorders		
Hypocalcaemia † 1		
# participants affected / at risk	**1/2660 (0.04%)**	**0/1326 (0.00%)**
# events	**1**	**0**
Hypokalaemia † 1		
# participants affected / at risk	**1/2660 (0.04%)**	**0/1326 (0.00%)**
# events	**1**	**0**
Hyponatraemia † 1		
# participants affected / at risk	**1/2660 (0.04%)**	**0/1326 (0.00%)**
# events	**1**	**0**
Metabolic acidosis † 1		
# participants affected / at risk	**1/2660 (0.04%)**	**0/1326 (0.00%)**
# events	**1**	**0**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Basal cell carcinoma † 1		
# participants affected / at risk	**1/2660 (0.04%)**	**0/1326 (0.00%)**
# events	**1**	**0**
Breast cancer † 1		

# participants affected / at risk	1/2660 (0.04%)	0/1326 (0.00%)
# events	1	0
Breast cancer metastatic † 1		
# participants affected / at risk	1/2660 (0.04%)	0/1326 (0.00%)
# events	1	0
Nervous system disorders		
Cervicobrachial syndrome † 1		
# participants affected / at risk	1/2660 (0.04%)	0/1326 (0.00%)
# events	1	0
Hypoxic-ischaemic encephalopathy † 1		
# participants affected / at risk	1/2660 (0.04%)	0/1326 (0.00%)
# events	1	0
Migraine with aura † 1		
# participants affected / at risk	1/2660 (0.04%)	1/1326 (0.08%)
# events	1	1
Post-traumatic headache † 1		
# participants affected / at risk	1/2660 (0.04%)	0/1326 (0.00%)
# events	1	0
VIIth nerve paralysis † 1		
# participants affected / at risk	0/2660 (0.00%)	1/1326 (0.08%)
# events	0	1
Pregnancy, puerperium and perinatal conditions		
Abortion spontaneous † 1		
# participants affected / at risk	1/2660 (0.04%)	0/1326 (0.00%)
# events	1	0
Ectopic pregnancy † 1		
# participants affected / at risk	0/2660 (0.00%)	1/1326 (0.08%)
# events	0	1
Umbilical cord prolapse † 1		
# participants affected / at risk	0/2660 (0.00%)	1/1326 (0.08%)
# events	0	1
Psychiatric disorders		
Acute stress disorder † 1		
# participants affected / at risk	0/2660 (0.00%)	1/1326 (0.08%)
# events	0	1
Anxiety † 1		
# participants affected / at risk	1/2660 (0.04%)	0/1326 (0.00%)
# events	1	0
Depression † 1		
# participants affected / at risk	2/2660 (0.08%)	0/1326 (0.00%)
# events	2	0
Mental status changes † 1		
# participants affected / at risk	1/2660 (0.04%)	0/1326 (0.00%)
# events	1	0
† 1		

Suicidal ideation		
# participants affected / at risk	**1/2660 (0.04%)**	**1/1326 (0.08%)**
# events	**1**	**1**
Renal and urinary disorders		
Calculus urinary † 1		
# participants affected / at risk	**1/2660 (0.04%)**	**0/1326 (0.00%)**
# events	**1**	**0**
Nephrolithiasis † 1		
# participants affected / at risk	**0/2660 (0.00%)**	**1/1326 (0.08%)**
# events	**0**	**1**
Renal failure † 1		
# participants affected / at risk	**1/2660 (0.04%)**	**0/1326 (0.00%)**
# events	**1**	**0**
Reproductive system and breast disorders		
Endometriosis † 1		
# participants affected / at risk	**1/2660 (0.04%)**	**0/1326 (0.00%)**
# events	**1**	**0**
Respiratory, thoracic and mediastinal disorders		
Asthma † 1		
# participants affected / at risk	**1/2660 (0.04%)**	**0/1326 (0.00%)**
# events	**1**	**0**
Dyspnoea † 1		
# participants affected / at risk	**1/2660 (0.04%)**	**0/1326 (0.00%)**
# events	**1**	**0**
Non-cardiogenic pulmonary oedema † 1		
# participants affected / at risk	**1/2660 (0.04%)**	**0/1326 (0.00%)**
# events	**1**	**0**
Respiratory acidosis † 1		
# participants affected / at risk	**1/2660 (0.04%)**	**0/1326 (0.00%)**
# events	**1**	**0**
Respiratory failure † 1		
# participants affected / at risk	**1/2660 (0.04%)**	**0/1326 (0.00%)**
# events	**1**	**0**

† Events were collected by systematic assessment

1 Term from vocabulary, MedDRA 13.0

Other Adverse Events

Hide Other Adverse Events

Time Frame	Up to 14 days after the last dose of study drug (Up to 6.5 months)
Additional Description	APaT population, which included all randomized participants who took at least 1 dose of study drug. Participants were included in the treatment arm corresponding to the study treatment actually taken. Participants who took both study treatments were included in the telcagepant 140 mg treatment arm. Presentation includes clinical and laboratory AEs.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Telcagepant 140 mg	Telcagepant 140 mg was administered once daily at bedtime for 7 consecutive days each month, beginning at the onset of menses, for up to 6 months. Dosing could begin up to 3 days prior to menses onset if prodromal symptoms reliably predicted onset of menses.
Placebo	Placebo was administered once daily at bedtime for 7 consecutive days each month, beginning at the onset of menses, for up to 6 months. Dosing could begin up to 3 days prior to menses onset if prodromal symptoms reliably predicted onset of menses.

Other Adverse Events

	Telcagepant 140 mg	Placebo
Total, other (not including serious) adverse events		
# participants affected / at risk	**819/2660 (30.79%)**	**413/1326 (31.15%)**
Gastrointestinal disorders		
Diarrhoea † 1		
# participants affected / at risk	**186/2660 (6.99%)**	**90/1326 (6.79%)**
# events	**292**	**128**
Dry mouth † 1		
# participants affected / at risk	**174/2660 (6.54%)**	**85/1326 (6.41%)**
# events	**359**	**168**
Nausea † 1		
# participants affected / at risk	**270/2660 (10.15%)**	**165/1326 (12.44%)**
# events	**467**	**264**
General disorders		
Fatigue † 1		
# participants affected / at risk	**135/2660 (5.08%)**	**65/1326 (4.90%)**
# events	**194**	**130**
Infections and infestations		
Nasopharyngitis † 1		
# participants affected / at risk	**190/2660 (7.14%)**	**102/1326 (7.69%)**
# events	**226**	**122**
Nervous system disorders		
Dizziness † 1		
# participants affected / at risk	**204/2660 (7.67%)**	**100/1326 (7.54%)**
# events	**340**	**166**

† Events were collected by systematic assessment

1 Term from vocabulary, MedDRA 13.0

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. Any information identified by the Sponsor as confidential must be deleted prior to submission. Sponsor review can be expedited to meet publication timelines.

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:

Ho TW, Ho AP, Ge YJ, Assaid C, Gottwald R, MacGregor EA, Mannix LK, van Oosterhout WP, Koppenhaver J, Lines C, Ferrari MD, Michelson D. Randomized controlled trial of the CGRP receptor antagonist telcagepant for prevention of headache in women with perimenstrual migraine. Cephalalgia. 2016 Feb;36(2):148-61. doi: 10.1177/0333102415584308. Epub 2015 Apr 29.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT01125774 History of Changes
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Study First Received:	May 17, 2010
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Last Updated:	June 30, 2015
Health Authority:	United States: Food and Drug Administration

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