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A Study to Test the Safety and Effectiveness of MK-0974 (Telcagepant) Co-administered With Ibuprofen or Acetaminophen in Patients With Migraines With or Without Aura (MK-0974-046)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00758836

First received: September 23, 2008
Last updated: July 9, 2015
Last verified: July 2015
History of Changes

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Purpose

This study will test the safety and how effective telcagepant is when taken with ibuprofen or acetaminophen in participants with migraine with or without aura. The primary study hypothesis is that at least one drug combination is superior to telecagepant alone in the treatment of acute migraines.

Condition	Intervention	Phase
Migraine	Drug: placebo Drug: ibuprofen Drug: acetominophen Drug: telcagepant	Phase 2

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 Phase IIa Randomized, Double-Blind, Parallel-Group, Placebo and Active-Controlled, Clinical Trial to Study the Efficacy and Safety of MK0974 Co-administered With Ibuprofen or Acetaminophen in Patients With Migraine With or Without Aura

Resource links provided by NLM:

MedlinePlus related topics: Migraine

Drug Information available for: Acetaminophen Ibuprofen Ibuprofen sodium Ibuprofen lysine

U.S. FDA Resources

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

Primary Outcome Measures:

- Percentage of Participants With Pain Freedom at Two Hours Post-dose [Time Frame: 2 hours post-dose] [Designated as safety issue: No]

  Pain severity was rated by the participants in a paper diary by grade; Grade 0 (no pain), Grade 1 (mild pain), Grade 2 (moderate pain), and Grade 3 (severe pain). Pain freedom was defined as a reduction in pain severity from moderate to severe migraine headache (Grade 2 or 3) to no pain (Grade 0).

- Number of Participants Experiencing Adverse Events Within 48 Hours Post-dose (Count ≥4 in One or More Treatment Groups) [Time Frame: Up to 48 hours post-dose] [Designated as safety issue: Yes]

  An adverse event is any unfavorable and unintended change in the structure, function, or chemistry of the body whether or not considered related to the study treatment.

- Number of Participants Experiencing Adverse Events Within 14 Days Post-dose (Count ≥4 in One or More Treatment Groups) [Time Frame: Up to 14 days post-dose] [Designated as safety issue: Yes]

  An adverse event is any unfavorable and unintended change in the structure, function, or chemistry of the body whether or not considered related to the study treatment.

Secondary Outcome Measures:

- Percentage of Participants With Pain Relief at 2 Hours Post-dose. [Time Frame: 2 hours post-dose] [Designated as safety issue: No]

  Pain severity was rated by the participants in a paper diary by grade; Grade 0 (no pain), Grade 1 (mild pain), Grade 2 (moderate pain), and Grade 3 (severe pain). Pain relief was defined as a reduction in pain severity from moderate to severe migraine headache (Grade 2 or 3) to mild or none (Grade 1 or 0).

Enrollment:	683
Study Start Date:	December 2008
Study Completion Date:	August 2009
Primary Completion Date:	August 2009 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Placebo Comparator: Placebo Participants take two placebo tablets and two placebo capsules, orally, at onset of migraine	Drug: placebo
Experimental: Telcagepant 280 mg +Ibuprofen 400 mg Participants take one telcagepant 280 mg tablet, one ibuprofen 400 mg tablet, and two placebo capsules, orally, at onset of migraine	Drug: ibuprofen Drug: telcagepant Other Name: MK-0974
Experimental: Telcagepant 280 mg +APAP 1000 mg Participants take one telcagepant 280 mg tablet, one placebo tablet, and two 500-mg APAP capsules, orally, at onset of migraine	Drug: acetominophen Other Name: N-acetyl-p-aminophenol (APAP) Drug: telcagepant Other Name: MK-0974
Placebo Comparator: Telcagepant 280 mg Participants take one telcagepant 280 mg tablet, one placebo tablet, and two placebo capsules, orally, at onset of migraine	Drug: telcagepant Other Name: MK-0974

Eligibility

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

Criteria

Inclusion Criteria:

- Must be 18 years of age or older
- History of migraine with or without aura for more than 1 year with 1-8 moderate or severe migraine attacks per month in the 2 months prior to starting in the study
- Willing to stay awake for at least 2 hours after taking study drug
- Able to read, understand and complete questionnaires and diaries

Exclusion Criteria:

- Breast-feeding, pregnant, or plan to become pregnant during the study
- Not able to tell migraine attack from other headaches
- Older than 50 years of age at migraine onset
- Have more than 15 headache days per month or have taken medication for acute headache on more than 10 days per month in any of the 3 months before starting in the study
- History of gastric or small intestinal surgery
- History of heart attack, stroke, unstable angina, coronary artery bypass surgery or transient ischemic attack in the 3 months before starting in the study
- Currently participating or have participated in a study with in investigational compound or device in the last 30 days

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: NCT00758836

Sponsors and Collaborators

Merck Sharp & Dohme Corp.

Investigators

Study Director: Medical Monitor Merck Sharp & Dohme Corp.

More Information

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

Hewitt DJ, Martin V, Lipton RB, Brandes J, Ceesay P, Gottwald R, Schaefer E, Lines C, Ho TW. Randomized controlled study of telcagepant plus ibuprofen or acetaminophen in migraine. Headache. 2011 Apr;51(4):533-43. doi: 10.1111/j.1526-4610.2011.01860.x.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00758836 History of Changes
Other Study ID Numbers:	0974-046 2008_551 CTRI/2009/091/000291
Study First Received:	September 23, 2008
Results First Received:	July 18, 2014
Last Updated:	July 9, 2015
Health Authority:	United States: Food and Drug Administration

Additional relevant MeSH terms:

Migraine Disorders	Antipyretics
Brain Diseases	Antirheumatic Agents
Central Nervous System Diseases	Central Nervous System Agents
Headache Disorders	Cyclooxygenase Inhibitors
Headache Disorders, Primary	Enzyme Inhibitors
Nervous System Diseases	Molecular Mechanisms of Pharmacological Action
Acetaminophen	Peripheral Nervous System Agents
Ibuprofen	Pharmacologic Actions

Analgesics
Analgesics, Non-Narcotic
Anti-Inflammatory Agents
Anti-Inflammatory Agents, Non-Steroidal
Physiological Effects of Drugs
Sensory System Agents
Therapeutic Uses

ClinicalTrials.gov processed this record on May 08, 2016

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A Study to Test the Safety and Effectiveness of MK-0974 (Telcagepant) Co-administered With Ibuprofen or Acetaminophen in Patients With Migraines With or Without Aura (MK-0974-046)

This study has been completed.

Sponsor:
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First received: September 23, 2008
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Results First Received: July 18, 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: placebo Drug: ibuprofen Drug: acetominophen Drug: telcagepant

Participant Flow

Hide Participant Flow

Recruitment Details

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

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
No text entered.

Reporting Groups

	Description
Placebo	Participants take two placebo tablets and two placebo capsules, orally, at onset of migraine
Telcagepant 280 mg +Ibuprofen 400 mg	Participants take one telcagepant 280 mg tablet, one ibuprofen 400 mg tablet, and two placebo capsules, orally, at onset of migraine
Telcagepant 280 mg +APAP 1000 mg	Participants take one telcagepant 280 mg tablet, one placebo tablet, and two 500-mg APAP capsules, orally, at onset of migraine
Telcagepant 280 mg	Participants take one telcagepant 280 mg tablet, one placebo tablet, and two placebo capsules, orally, at onset of migraine

Participant Flow: Overall Study

	Placebo	Telcagepant 280 mg +Ibuprofen 400 mg	Telcagepant 280 mg +APAP 1000 mg	Telcagepant 280 mg
STARTED	**171**	**171**	**171**	**170**
Treated	**147**	**145**	**133**	**138**
COMPLETED	**147**	**145**	**133**	**138**
NOT COMPLETED	**24**	**26**	**38**	**32**

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Placebo	Participants take two placebo tablets and two placebo capsules, orally, at onset of migraine
Telcagepant 280 mg +Ibuprofen 400 mg	Participants take one telcagepant 280 mg tablet, one ibuprofen 400 mg tablet, and two placebo capsules, orally, at onset of migraine
Telcagepant 280 mg +APAP 1000 mg	Participants take one telcagepant 280 mg tablet, one placebo tablet, and two 500-mg APAP capsules, orally, at onset of migraine
Telcagepant 280 mg	Participants take one telcagepant 280 mg tablet, one placebo tablet, and two placebo capsules, orally, at onset of migraine
Total	Total of all reporting groups

Baseline Measures

	Placebo	Telcagepant 280 mg +Ibuprofen 400 mg	Telcagepant 280 mg +APAP 1000 mg	Telcagepant 280 mg	Total
Number of Participants [units: participants]	**171**	**171**	**171**	**170**	**683**

Age, Customized [units: participants]					
<20 years	**4**	**0**	**3**	**3**	**10**
20-29 years	**34**	**43**	**32**	**33**	**142**
30-39 years	**33**	**47**	**37**	**53**	**170**
40-49 years	**58**	**51**	**49**	**51**	**209**
50-59 years	**32**	**19**	**42**	**23**	**116**
60-64 years	**4**	**6**	**6**	**2**	**18**
>=65 years	**6**	**5**	**2**	**5**	**18**
Gender [units: participants]					
Female	**150**	**139**	**149**	**145**	**583**
Male	**21**	**32**	**22**	**25**	**100**

Outcome Measures

Hide All Outcome Measures

1. Primary: Percentage of Participants With Pain Freedom at Two Hours Post-dose [Time Frame: 2 hours post-dose]

Measure Type	Primary
Measure Title	Percentage of Participants With Pain Freedom at Two Hours Post-dose
Measure Description	Pain severity was rated by the participants in a paper diary by grade; Grade 0 (no pain), Grade 1 (mild pain), Grade 2 (moderate pain), and Grade 3 (severe pain). Pain freedom was defined as a reduction in pain severity from moderate to severe migraine headache (Grade 2 or 3) to no pain (Grade 0).
Time Frame	2 hours post-dose
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The Full Analysis Set (FAS) comprised participants who were treated and had a baseline assessment and at least one post-dose assessment up to or including the 2-hour time point. Missing data were imputed by using a Last Observation Carried Forward (LOCF) approach; baseline values were not carried forward to impute the missing post-treatment data.

Reporting Groups

	Description
Placebo	Participants take two placebo tablets and two placebo capsules, orally, at onset of migraine
Telcagepant 280 mg +Ibuprofen 400 mg	Participants take one telcagepant 280 mg tablet, one ibuprofen 400 mg tablet, and two placebo capsules, orally, at onset of migraine
Telcagepant 280 mg +APAP 1000 mg	Participants take one telcagepant 280 mg tablet, one placebo tablet, and two 500-mg APAP capsules, orally, at onset of migraine
Telcagepant 280 mg	Participants take one telcagepant 280 mg tablet, one placebo tablet, and two placebo capsules, orally, at onset of migraine

Measured Values

	Placebo	Telcagepant 280 mg +Ibuprofen 400 mg	Telcagepant 280 mg +APAP 1000 mg	Telcagepant 280 mg
Number of Participants Analyzed [units: participants]	147	145	133	138
Percentage of Participants With Pain Freedom at Two Hours Post-dose [units: Percentage of Participants]	10.9	35.2	38.3	31.2

Statistical Analysis 1 for Percentage of Participants With Pain Freedom at Two Hours Post-dose

Groups [1]	Placebo vs. Telcagepant 280 mg +Ibuprofen 400 mg
Method [2]	Miettinen and Nurminen
P Value [3]	<0.001
Proportion difference [4]	24.5
90% Confidence Interval	16.7 to 32.2

[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:
	Miettinen and Nurminen method for independent binomial distribution stratified by baseline severity.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for Percentage of Participants With Pain Freedom at Two Hours Post-dose

Groups [1]	Placebo vs. Telcagepant 280 mg +APAP 1000 mg
Method [2]	Miettinen and Nurminen
P Value [3]	<0.001
Proportion difference [4]	27.7
90% Confidence Interval	19.6 to 35.8

[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:
	Miettinen and Nurminen method for independent binomal distribution stratified by baseline severity.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 3 for Percentage of Participants With Pain Freedom at Two Hours Post-dose

Groups [1]	Placebo vs. Telcagepant 280 mg
Method [2]	Miettinen and Nurminen
P Value [3]	<0.001
Proportion difference [4]	20.4
90% Confidence Interval	12.6 to 28.2

[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:
	Miettinen and Nurminen method for independent binomal distribution stratified by baseline severity.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 4 for Percentage of Participants With Pain Freedom at Two Hours Post-dose

Groups [1]	Telcagepant 280 mg +Ibuprofen 400 mg vs. Telcagepant 280 mg
Method [2]	Miettinen and Nurminen
P Value [3]	0.449
Proportion differenece [4]	4.2
90% Confidence Interval	-5.0 to 13.3

[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:
	Miettinen and Nurminen method for independent binomal distribution stratified by baseline severity.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 5 for Percentage of Participants With Pain Freedom at Two Hours Post-dose

Groups [1]	Telcagepant 280 mg +APAP 1000 mg vs. Telcagepant 280 mg

Method [2]	Miettinen and Nurminen
P Value [3]	0.182
Proportion difference [4]	7.7
90% Confidence Interval	-1.8 to 17.1

[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:
	Miettinen and Nurminen method for independent binomal distribution stratified by baseline severity.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

2. Primary: Number of Participants Experiencing Adverse Events Within 48 Hours Post-dose (Count ≥4 in One or More Treatment Groups) [Time Frame: Up to 48 hours post-dose]

Measure Type	Primary
Measure Title	Number of Participants Experiencing Adverse Events Within 48 Hours Post-dose (Count ≥4 in One or More Treatment Groups)
Measure Description	An adverse event is any unfavorable and unintended change in the structure, function, or chemistry of the body whether or not considered related to the study treatment.
Time Frame	Up to 48 hours post-dose
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 (one participant assigned to the Telcagepant 280 mg arm only took the placebo tablet and is included in the Placebo arm for adverse event reporting).

Reporting Groups

	Description
Placebo	Participants take two placebo tablets and two placebo capsules, orally, at onset of migraine
Telcagepant 280 mg +Ibuprofen 400 mg	Participants take one telcagepant 280 mg tablet, one ibuprofen 400 mg tablet, and two placebo capsules, orally, at onset of migraine
Telcagepant 280 mg +APAP 1000 mg	Participants take one telcagepant 280 mg tablet, one placebo tablet, and two 500-mg APAP capsules, orally, at onset of migraine
Telcagepant 280 mg	Participants take one telcagepant 280 mg tablet, one placebo tablet, and two placebo capsules, orally, at onset of migraine

Measured Values

	Placebo	Telcagepant 280 mg +Ibuprofen 400 mg	Telcagepant 280 mg +APAP 1000 mg	Telcagepant 280 mg
Number of Participants Analyzed [units: participants]	**148**	**145**	**133**	**137**
Number of Participants Experiencing Adverse Events Within 48 Hours Post-dose (Count ≥4 in One or More Treatment Groups) [units: Participants]	**27**	**44**	**42**	**34**

No statistical analysis provided for Number of Participants Experiencing Adverse Events Within 48 Hours Post-dose (Count ≥4 in One or More Treatment Groups)

3. Primary: Number of Participants Experiencing Adverse Events Within 14 Days Post-dose (Count ≥4 in One or More Treatment Groups) [Time Frame: Up to 14 days post-dose]

Measure Type	Primary
Measure Title	Number of Participants Experiencing Adverse Events Within 14 Days Post-dose (Count ≥4 in One or More Treatment Groups)
Measure Description	An adverse event is any unfavorable and unintended change in the structure, function, or chemistry of the body whether or not considered related to the study treatment.
Time Frame	Up to 14 days post-dose
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 (one participant assigned to the Telcagepant 280 mg arm only took the placebo tablet and is included in the Placebo arm for adverse event reporting).

Reporting Groups

	Description
Placebo	Participants take two placebo tablets and two placebo capsules, orally, at onset of migraine
Telcagepant 280 mg +Ibuprofen 400 mg	Participants take one telcagepant 280 mg tablet, one ibuprofen 400 mg tablet, and two placebo capsules, orally, at onset of migraine
Telcagepant 280 mg +APAP 1000 mg	Participants take one telcagepant 280 mg tablet, one placebo tablet, and two 500-mg APAP capsules, orally, at onset of migraine
Telcagepant 280 mg	Participants take one telcagepant 280 mg tablet, one placebo tablet, and two placebo capsules, orally, at onset of migraine

Measured Values

	Placebo	Telcagepant 280 mg +Ibuprofen 400 mg	Telcagepant 280 mg +APAP 1000 mg	Telcagepant 280 mg
Number of Participants Analyzed [units: participants]	**148**	**145**	**133**	**137**
Number of Participants Experiencing Adverse Events Within 14 Days Post-dose (Count ≥4 in One or More Treatment Groups) [units: participants]	**31**	**46**	**46**	**37**

No statistical analysis provided for Number of Participants Experiencing Adverse Events Within 14 Days Post-dose (Count ≥4 in One or More Treatment Groups)

4. Secondary: Percentage of Participants With Pain Relief at 2 Hours Post-dose. [Time Frame: 2 hours post-dose]

Measure Type	Secondary
Measure Title	Percentage of Participants With Pain Relief at 2 Hours Post-dose.
Measure Description	Pain severity was rated by the participants in a paper diary by grade; Grade 0 (no pain), Grade 1 (mild pain), Grade 2 (moderate pain), and Grade 3 (severe pain). Pain relief was defined as a reduction in pain severity from moderate to severe migraine headache (Grade 2 or 3) to mild or none (Grade 1 or 0).
Time Frame	2 hours post-dose
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The FAS comprised participants who were treated and had a baseline assessment and at least one post-dose assessment up to or including the 2-hour time point. Missing data were imputed by using a Last Observation Carried Forward (LOCF) approach; baseline values were not carried forward to impute the missing post-treatment data.

Reporting Groups

	Description
Placebo	Participants take two placebo tablets and two placebo capsules, orally, at onset of migraine
Telcagepant 280 mg +Ibuprofen 400 mg	Participants take one telcagepant 280 mg tablet, one ibuprofen 400 mg tablet, and two placebo capsules, orally, at onset of migraine
Telcagepant 280 mg +APAP 1000 mg	Participants take one telcagepant 280 mg tablet, one placebo tablet, and two 500-mg APAP capsules, orally, at onset of migraine
Telcagepant 280 mg	Participants take one telcagepant 280 mg tablet, one placebo tablet, and two placebo capsules, orally, at onset of migraine

Measured Values

	Placebo	**Telcagepant 280 mg +Ibuprofen 400 mg**	**Telcagepant 280 mg +APAP 1000 mg**	**Telcagepant 280 mg**
Number of Participants Analyzed [units: participants]	**147**	**145**	**133**	**138**
Percentage of Participants With Pain Relief at 2 Hours Post-dose. [units: Percentage of Participants]	**30.6**	**71.0**	**69.9**	**65.2**

Statistical Analysis 1 for Percentage of Participants With Pain Relief at 2 Hours Post-dose.

Groups [1]	Placebo vs. Telcagepant 280 mg +Ibuprofen 400 mg
Method [2]	Miettinen and Nurminen
P Value [3]	<0.001

Proportion difference [4]	40.8
90% Confidence Interval	31.9 to 49.0

[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:
	Miettinen and Nurminen method for independent binomal distribution stratified by baseline severity.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for Percentage of Participants With Pain Relief at 2 Hours Post-dose.

Groups [1]	Placebo vs. Telcagepant 280 mg +APAP 1000 mg
Method [2]	Miettinen and Nurminen
P Value [3]	<0.001
Proportion difference [4]	39.9
90% Confidence Interval	30.5 to 48.5

[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:
	Miettinen and Nurminen method for independent binomal distribution stratified by baseline severity.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 3 for Percentage of Participants With Pain Relief at 2 Hours Post-dose.

Groups [1]	Telcagepant 280 mg +Ibuprofen 400 mg vs. Telcagepant 280 mg
Method [2]	Miettinen and Nurminen
P Value [3]	0.265
Proportion difference [4]	6.1
90% Confidence Interval	-2.9 to 14.9

[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:
	Miettinen and Nurminen method for independent binomal distribution stratified by baseline severity.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 4 for Percentage of Participants With Pain Relief at 2 Hours Post-dose.

Groups [1]	Telcagepant 280 mg +APAP 1000 mg vs. Telcagepant 280 mg
Method [2]	Miettinen and Nurminen
P Value [3]	0.362
Proportion difference [4]	5.2
90% Confidence Interval	-4.2 to 14.5

[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:
	Miettinen and Nurminen method for independent binomal distribution stratified by baseline severity.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 5 for Percentage of Participants With Pain Relief at 2 Hours Post-dose.

Groups [1]	Placebo vs. Telcagepant 280 mg
Method [2]	Miettinen and Nurminen
P Value [3]	<0.001
Proportion difference [4]	34.7
90% Confidence Interval	25.3 to 43.4

[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:
	Miettinen and Nurminen method for independent binomal distribution stratified by baseline severity.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

[4]	Other relevant estimation information:
	No text entered.

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Up to 14 days after the dose was taken.
Additional Description	One participant randomly assigned to the Telcagepant 280 mg arm took only the placebp tablet and is included in the Placebo arm for adverse event reporting.

Reporting Groups

	Description
Placebo	Participants take two placebo tablets and two placebo capsules, orally, at onset of migraine
Telcagepant 280 mg +Ibuprofen 400 mg	Participants take one telcagepant 280 mg tablet, one ibuprofen 400 mg tablet, and two placebo capsules, orally, at onset of migraine
Telcagepant 280 mg +APAP 1000 mg	Participants take one telcagepant 280 mg tablet, one placebo tablet, and two 500-mg APAP capsules, orally, at onset of migraine
Telcagepant 280 mg	Participants take one telcagepant 280 mg tablet, one placebo tablet, and two placebo capsules, orally, at onset of migraine

Serious Adverse Events

	Placebo	Telcagepant 280 mg +Ibuprofen 400 mg	Telcagepant 280 mg +APAP 1000 mg	Telcagepant 280 mg
Total, serious adverse events				
# participants affected / at risk	**0/148 (0.00%)**	**0/145 (0.00%)**	**0/133 (0.00%)**	**0/137 (0.00%)**

Other Adverse Events

Hide Other Adverse Events

Time Frame	Up to 14 days after the dose was taken.
Additional Description	One participant randomly assigned to the Telcagepant 280 mg arm took only the placebp tablet and is included in the Placebo arm for adverse event reporting.

Frequency Threshold

Threshold above which other adverse events are reported	0%

Reporting Groups

	Description
Placebo	Participants take two placebo tablets and two placebo capsules, orally, at onset of migraine

Telcagepant 280 mg +Ibuprofen 400 mg	Participants take one telcagepant 280 mg tablet, one ibuprofen 400 mg tablet, and two placebo capsules, orally, at onset of migraine
Telcagepant 280 mg +APAP 1000 mg	Participants take one telcagepant 280 mg tablet, one placebo tablet, and two 500-mg APAP capsules, orally, at onset of migraine
Telcagepant 280 mg	Participants take one telcagepant 280 mg tablet, one placebo tablet, and two placebo capsules, orally, at onset of migraine

Other Adverse Events

	Placebo	Telcagepant 280 mg +Ibuprofen 400 mg	Telcagepant 280 mg +APAP 1000 mg	Telcagepant 280 mg
Total, other (not including serious) adverse events				
# participants affected / at risk	**12/148 (8.11%)**	**23/145 (15.86%)**	**16/133 (12.03%)**	**16/137 (11.68%)**
Gastrointestinal disorders				
Nausea † 1				
# participants affected / at risk	**8/148 (5.41%)**	**9/145 (6.21%)**	**5/133 (3.76%)**	**6/137 (4.38%)**
# events	**8**	**9**	**5**	**6**
General disorders				
Fatigue † 1				
# participants affected / at risk	**1/148 (0.68%)**	**8/145 (5.52%)**	**7/133 (5.26%)**	**4/137 (2.92%)**
# events	**1**	**9**	**7**	**4**
Nervous system disorders				
Somnolence † 1				
# participants affected / at risk	**3/148 (2.03%)**	**8/145 (5.52%)**	**5/133 (3.76%)**	**6/137 (4.38%)**
# events	**3**	**8**	**5**	**6**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 11.1

Limitations and Caveats

Hide Limitations and Caveats

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

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.
There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial

results after the trial is completed.

The agreement is:

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

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

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

Restriction Description: The SPONSOR must have the opportunity to review all proposed abstracts, manuscripts, or presentations regarding this study 60 days prior to submission for publication/presentation. Any information identified by the Sponsor as confidential must be deleted prior to submission.

Results Point of Contact:

Name/Title: Senior Vice President, Global Clinical Development
Organization: Merck Sharp & Dohme Corp
phone: 1-800-672-6372
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Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

Hewitt DJ, Martin V, Lipton RB, Brandes J, Ceesay P, Gottwald R, Schaefer E, Lines C, Ho TW. Randomized controlled study of telcagepant plus ibuprofen or acetaminophen in migraine. Headache. 2011 Apr;51(4):533-43. doi: 10.1111/j.1526-4610.2011.01860.x.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00758836 History of Changes
Other Study ID Numbers:	0974-046 2008_551 (Other Identifier: Merck Registration Number) CTRI/2009/091/000291 (Registry Identifier: CTRI)
Study First Received:	September 23, 2008
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Health Authority:	United States: Food and Drug Administration

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