Safety and Efficacy Study of MK0974 in the Acute Migraine (0974-016)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00432237

First received: February 5, 2007
Last updated: June 8, 2015
Last verified: June 2015
History of Changes

Purpose

The purpose of this study is to investigate the efficacy and safety of MK0974 compared to a placebo for acute migraine.

Condition	Intervention	Phase
Migraine	Drug: MK0974 50 mg Drug: MK0974 150 mg Drug: MK0974 300 mg Drug: Comparator: Placebo	Phase 3

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

Official Title: A Phase III, Multicenter, Randomized, Placebo-Controlled Clinical Trial to Study the Safety and Efficacy of Oral MK0974 in the Acute Treatment of Migraine With or Without Aura

Resource links provided by NLM:

MedlinePlus related topics: Migraine

U.S. FDA Resources

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

Primary Outcome Measures:

- Number of Patients Reporting Pain Freedom at 2 Hours Postdose [Time Frame: 2 hours post dose] [Designated as safety issue: No]

Pain Freedom was defined as a reduction of a Grade 2 or 3 severity migraine at baseline to a no pain (Grade 0) at 2 hours post dose. Headache severity was recorded by the patient in a diary. 0=no pain; 1=mild pain; 2=moderate pain; 3=severe pain.

- Number of Patients Reporting Pain Relief at 2 Hours Post Dose [Time Frame: 2 hours post dose] [Designated as safety issue: No]

  Reduction of a Grade 2 or 3 severity migraine at baseline to mild or no pain (Grade 1 or 0) at 2 hours post dose. Headache severity was recorded by the patient in a diary. 0=no pain; 1=mild pain; 2=moderate pain; 3=severe pain.

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

  Respective experience (yes/no) of migraine-associated symptoms (including photophobia) was recorded by the patient in a diary.

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

  Respective experience (yes/no) of migraine-associated symptoms (including phonophobia) was recorded by the patient in a diary.

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

  Respective experience (yes/no) of migraine-associated symptoms (including nausea) was recorded by the patient in a diary.

Secondary Outcome Measures:

- Number of Patients Who Have Sustained Pain-Freedom From 2 to 24 Hours Postdose [Time Frame: 2 to 24 hours postdose] [Designated as safety issue: No]

  Pain Freedom at 2 hours postdose, with no administration of any rescue medication and no occurrence thereafter of a mild/moderate/severe headache during the 24 hours after dosing with study medication.

- Number of Patients Who Have Total Migraine Freedom 2 to 24 Hours Postdose [Time Frame: 2 to 24 hours postdose] [Designated as safety issue: No]

  Pain Freedom and no migraine-associated symptoms at 2 hours postdose, with no administration of any rescue medication and no occurrence thereafter of a mild/moderate/severe headache or migraine-associated symptom during the 24 hours after dosing with study medication.

- Number of Patients Who Have Total Migraine Freedom 2 Hours Postdose [Time Frame: 2 hours postdose] [Designated as safety issue: No]

  Pain Freedom and no migraine-associated symptoms at 2 hours postdose.

Enrollment:	1703
Study Start Date:	March 2007
Study Completion Date:	December 2007
Primary Completion Date:	December 2007 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: MK0974 50 mg MK0974 50 mg; one orally-administered dose, plus an optional second dose (MK0974 50 mg) to treat a single moderate-to-severe migraine attack	Drug: MK0974 50 mg Other Name: MK0974
Experimental: MK0974 150 mg MK0974 150 mg; one orally-administered dose, plus an optional second dose (MK0974 150 mg) to treat a single moderate-to-severe migraine attack	Drug: MK0974 150 mg Other Name: MK0974
Experimental: MK0974 300 mg MK0974 300 mg; one orally-administered dose, plus an optional second dose (MK0974 300 mg or placebo) to treat a single moderate-to-severe migraine attack	Drug: MK0974 300 mg Other Name: MK0974
Placebo Comparator: Placebo Placebo; one orally-administered dose, plus an optional second dose (placebo) to treat a single moderate-to-severe migraine attack	Drug: Comparator: Placebo MK0974 50 mg soft gel capsule Placebo; MK0974 150 mg soft gel capsule Placebo; MK0974 300 mg soft gel capsule Placebo.

Eligibility

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

Criteria

Inclusion Criteria:

- Patient has at least 1 year history of migraine (with or without aura)
- Females of childbearing years must use acceptable contraception throughout trial

Exclusion Criteria:

- Patient is pregnant/breast-feeding (or is a female expecting to conceive during the study period)
- Patient has history or evidence of uncontrolled diabetes, or Human Immunodeficiency Virus (HIV) disease. Patient has uncontrolled cardiovascular disease
- Patient has major depression, other pain syndromes that might interfere with study assessments, psychiatric conditions, dementia, or significant neurological disorders (other than migraine)
- Patient has a history of gastric or small intestinal surgery or has a disease that causes malabsorption
- Patient has a history of cancer within the last 5 years

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT00432237

Sponsors and Collaborators

Merck Sharp & Dohme Corp.

Investigators

Study Director: Medical Monitor Merck Sharp & Dohme Corp.

More Information

Publications:

Connor KM, Shapiro RE, Diener HC, Lucas S, Kost J, Fan X, Fei K, Assaid C, Lines C, Ho TW. Randomized, controlled trial of telcagepant for the acute treatment of migraine. Neurology. 2009 Sep 22;73(12):970-7. doi: 10.1212/WNL.0b013e3181b87942.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00432237 History of Changes
Other Study ID Numbers:	0974-016 2006_526
Study First Received:	February 5, 2007
Results First Received:	July 19, 2010
Last Updated:	June 8, 2015
Health Authority:	United States: Food and Drug Administration

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 April 14, 2016

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Safety and Efficacy Study of MK0974 in the Acute Migraine (0974-016)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00432237

First received: February 5, 2007
Last updated: June 8, 2015
Last verified: June 2015
History of Changes

Results First Received: July 19, 2010

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Treatment
Condition:	Migraine
Interventions:	Drug: MK0974 50 mg Drug: MK0974 150 mg Drug: MK0974 300 mg Drug: Comparator: 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
There were 83 centers worldwide that participated: United States (36), Latin America (9), and Europe (38). First Patient Treated = 25 March 2007, and Last Patient Last Treatment = 29 November 2007.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
Participants were assessed, using the protocol inclusion and exclusion criteria, at Visit 1, and if eligible were randomized at that same visit.

Reporting Groups

	Description
MK0974 50 mg	MK0974 50 mg; one orally-administered dose, plus an optional second dose (MK0974 50 mg) to treat a single moderate-to-severe migraine attack
MK0974 150 mg	MK0974 150 mg; one orally-administered dose, plus an optional second dose (MK0974 150 mg) to treat a single moderate-to-severe migraine attack
MK0974 300 mg	MK0974 300 mg; one orally-administered dose, plus an optional second dose (MK0974 300 mg or placebo) to treat a single moderate-to-severe migraine attack
Placebo	Placebo; one orally-administered dose, plus an optional second dose (placebo) to treat a single moderate-to-severe migraine attack

Participant Flow: Overall Study

	MK0974 50 mg	MK0974 150 mg	MK0974 300 mg	Placebo
STARTED	244 [1]	485	484 [2]	490
Completed--With Data	176	381	370	365
Completed--No Data	1 [3]	3 [3]	5 [3]	1 [3]
COMPLETED	177	384	375	366
NOT COMPLETED	67	101	109	124
Adverse Event	0	0	0	1
Lack of Efficacy	0	0	0	1
Lost to Follow-up	10	10	18	18
Physician Decision	1	3	2	1
Pregnancy	0	1	0	0
Protocol Violation	13	10	11	8
Withdrawal by Subject	5	6	9	11
Lack of Qualifying Event	38	71	69	84

[1] 1 patient in the MK0974 50 mg group was treated but withdrew consent.
[2] 1 patient in the MK0974 300 mg group was treated but withdrew consent.
[3] For patients in this category, diaries were collected but lost prior to data entry.

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

MK0974 50 mg	MK0974 50 mg; one orally-administered dose, plus an optional second dose (MK0974 50 mg) to treat a single moderate-to-severe migraine attack The reported number of participants are all patients randomized who received study drug and completed the study.
MK0974 150 mg	MK0974 150 mg; one orally-administered dose, plus an optional second dose (MK0974 150 mg) to treat a single moderate-to-severe migraine attack The reported number of participants are all patients randomized who received study drug and completed the study.
MK0974 300 mg	MK0974 300 mg; one orally-administered dose, plus an optional second dose (MK0974 300 mg or placebo) to treat a single moderate-to-severe migraine attack The reported number of participants are all patients randomized who received study drug and completed the study.
Placebo	Placebo; one orally-administered dose, plus an optional second dose (placebo) to treat a single moderate-to-severe migraine attack The reported number of participants are all patients randomized who received study drug and completed the study.
Total	Total of all reporting groups

Baseline Measures

	MK0974 50 mg	MK0974 150 mg	MK0974 300 mg	Placebo	Total
Number of Participants [units: participants]	**177**	**381**	**371**	**365**	**1294**
Age [1] [units: years] Mean (Standard Deviation)	**41.4 (11.3)**	**41.6 (11.0)**	**41.8 (11.6)**	**41.9 (11.9)**	**41.7 (11.5)**
Gender [1] [units: participants]					
Female	**156**	**329**	**320**	**318**	**1123**
Male	**21**	**52**	**51**	**47**	**171**
Race/Ethnicity, Customized [1] [units: participants]					
White	**148**	**320**	**302**	**303**	**1073**
Black	**10**	**16**	**23**	**20**	**69**
Asian	**1**	**6**	**1**	**8**	**16**
American Indian or Alaska Native	**1**	**2**	**0**	**0**	**3**
Native Hawaiian or Other Pacific Islander	**0**	**0**	**1**	**0**	**1**
Multi-Racial	**17**	**37**	**44**	**33**	**131**
Missing	**0**	**0**	**0**	**1**	**1**
Baseline Severity [2] [units: Participants]					
Moderate	**108**	**254**	**237**	**235**	**834**
Severe	**69**	**127**	**133**	**130**	**459**
Baseline Severity missing	**0**	**0**	**1**	**0**	**1**

[1] Baseline Characteristics are for the subset of randomized patients who were treated

[2] Baseline severity was self-reported by the patient and recorded in the take-home diary. Patients were instructed not to dose until they had

experienced either a moderate or severe migraine, with migraine pain rated on a 4-point scale (No Pain=0, Mild Pain=1, Moderate Pain=2, Severe Pain=3). Baseline Characteristics are for the subset of randomized patients who were treated.

Outcome Measures

Hide All Outcome Measures

1. Primary: Number of Patients Reporting Pain Freedom at 2 Hours Postdose [Time Frame: 2 hours post dose]

Measure Type	Primary
Measure Title	Number of Patients Reporting Pain Freedom at 2 Hours Postdose
Measure Description	Pain Freedom was defined as a reduction of a Grade 2 or 3 severity migraine at baseline to a no pain (Grade 0) at 2 hours post dose. Headache severity was recorded by the patient in a diary. 0=no pain; 1=mild pain; 2=moderate pain; 3=severe pain.
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.
All randomized, treated patients who have at least one post-dose measurement at or prior to 2 hours.

Reporting Groups

	Description
MK0974 50 mg	MK0974 50 mg; one orally-administered dose, plus an optional second dose (MK0974 50 mg) to treat a single moderate-to-severe migraine attack
MK0974 150 mg	MK0974 150 mg; one orally-administered dose, plus an optional second dose (MK0974 150 mg) to treat a single moderate-to-severe migraine attack
MK0974 300 mg	MK0974 300 mg; one orally-administered dose, plus an optional second dose (MK0974 300 mg or placebo) to treat a single moderate-to-severe migraine attack
Placebo	Placebo; one orally-administered dose, plus an optional second dose (placebo) to treat a single moderate-to-severe migraine attack

Measured Values

	MK0974 50 mg	**MK0974 150 mg**	**MK0974 300 mg**	**Placebo**
Number of Participants Analyzed [units: participants]	**176**	**380**	**369**	**365**
Number of Patients Reporting Pain Freedom at 2 Hours Postdose [units: Participants]	**29**	**88**	**88**	**39**

Statistical Analysis 1 for Number of Patients Reporting Pain Freedom at 2 Hours Postdose

Groups [1]	MK0974 150 mg vs. Placebo
Method [2]	Regression, Logistic

P Value [3]	<0.001

[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:
	P-value constructed using a logistic model adjusting for baseline severity (moderate, severe), region (US, ex-US), treatment and age (continuous).
[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.

Statistical Analysis 2 for Number of Patients Reporting Pain Freedom at 2 Hours Postdose

Groups [1]	MK0974 300 mg vs. Placebo
Method [2]	Regression, Logistic
P Value [3]	<0.001

[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:
	P-value constructed using a logistic model adjusting for baseline severity (moderate, severe), region (US, ex-US), treatment and age (continuous).
[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.

2. Primary: Number of Patients Reporting Pain Relief at 2 Hours Post Dose [Time Frame: 2 hours post dose]

Measure Type	Primary
Measure Title	Number of Patients Reporting Pain Relief at 2 Hours Post Dose
Measure Description	Reduction of a Grade 2 or 3 severity migraine at baseline to mild or no pain (Grade 1 or 0) at 2 hours post dose. Headache severity was recorded by the patient in a diary. 0=no pain; 1=mild pain; 2=moderate pain; 3=severe pain.
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.
All randomized, treated patients who have at least one post-dose measurement at or prior to 2 hours.

Reporting Groups

	Description
MK0974 50 mg	MK0974 50 mg; one orally-administered dose, plus an optional second dose (MK0974 50 mg) to treat a single moderate-to-

	severe migraine attack
MK0974 150 mg	MK0974 150 mg; one orally-administered dose, plus an optional second dose (MK0974 150 mg) to treat a single moderate-to-severe migraine attack
MK0974 300 mg	MK0974 300 mg; one orally-administered dose, plus an optional second dose (MK0974 300 mg or placebo) to treat a single moderate-to-severe migraine attack
Placebo	Placebo; one orally-administered dose, plus an optional second dose (placebo) to treat a single moderate-to-severe migraine attack

Measured Values

	MK0974 50 mg	MK0974 150 mg	MK0974 300 mg	Placebo
Number of Participants Analyzed [units: participants]	**176**	**380**	**369**	**365**
Number of Patients Reporting Pain Relief at 2 Hours Post Dose [units: Participants]	**78**	**205**	**205**	**120**

Statistical Analysis 1 for Number of Patients Reporting Pain Relief at 2 Hours Post Dose

Groups [1]	MK0974 150 mg vs. Placebo
Method [2]	Regression, Logistic
P Value [3]	<0.001

[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:
	P-value constructed using a logistic model adjusting for baseline severity (moderate, severe), region (US, ex-US), treatment and age (continuous).
[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.

Statistical Analysis 2 for Number of Patients Reporting Pain Relief at 2 Hours Post Dose

Groups [1]	MK0974 300 mg vs. Placebo
Method [2]	Regression, Logistic
P Value [3]	<0.001

[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:
	P-value constructed using a logistic model adjusting for baseline severity (moderate, severe), region (US, ex-US), treatment and age (continuous).
[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.

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

Measure Type	Primary
Measure Title	Number of Patients Reporting Absence of Photophobia at 2 Hours Post Dose
Measure Description	Respective experience (yes/no) of migraine-associated symptoms (including photophobia) was recorded by the patient in a diary.
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.
All randomized, treated patients who have at least one post-dose measurement at or prior to 2 hours.

Reporting Groups

	Description
MK0974 50 mg	MK0974 50 mg; one orally-administered dose, plus an optional second dose (MK0974 50 mg) to treat a single moderate-to-severe migraine attack
MK0974 150 mg	MK0974 150 mg; one orally-administered dose, plus an optional second dose (MK0974 150 mg) to treat a single moderate-to-severe migraine attack
MK0974 300 mg	MK0974 300 mg; one orally-administered dose, plus an optional second dose (MK0974 300 mg or placebo) to treat a single moderate-to-severe migraine attack
Placebo	Placebo; one orally-administered dose, plus an optional second dose (placebo) to treat a single moderate-to-severe migraine attack

Measured Values

	MK0974 50 mg	MK0974 150 mg	MK0974 300 mg	Placebo
Number of Participants Analyzed [units: participants]	**176**	**380**	**369**	**365**
Number of Patients Reporting Absence of Photophobia at 2 Hours Post Dose [units: Participants]	**72**	**176**	**179**	**119**

Statistical Analysis 1 for Number of Patients Reporting Absence of Photophobia at 2 Hours Post Dose

Groups [1]	MK0974 150 mg vs. Placebo
Method [2]	Regression, Logistic
P Value [3]	<0.001

[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:
	P-value constructed using a logistic model adjusting for baseline severity (moderate, severe), region (US, ex-US), treatment and age (continuous).
[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.

Statistical Analysis 2 for Number of Patients Reporting Absence of Photophobia at 2 Hours Post Dose

Groups [1]	MK0974 300 mg vs. Placebo
Method [2]	Regression, Logistic
P Value [3]	<0.001

[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:
	P-value constructed using a logistic model adjusting for baseline severity (moderate, severe), region (US, ex-US), treatment and age (continuous).
[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. Primary: Number of Patients Reporting Absence of Phonophobia at 2 Hours Post Dose [Time Frame: 2 hours post dose]

Measure Type	Primary
Measure Title	Number of Patients Reporting Absence of Phonophobia at 2 Hours Post Dose
Measure Description	Respective experience (yes/no) of migraine-associated symptoms (including phonophobia) was recorded by the patient in a diary.
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.
All randomized, treated patients who have at least one post-dose measurement at or prior to 2 hours.

Reporting Groups

	Description
MK0974 50 mg	MK0974 50 mg; one orally-administered dose, plus an optional second dose (MK0974 50 mg) to treat a single moderate-to-severe migraine attack
MK0974 150 mg	MK0974 150 mg; one orally-administered dose, plus an optional second dose (MK0974 150 mg) to treat a single moderate-to-severe migraine attack

MK0974 300 mg	MK0974 300 mg; one orally-administered dose, plus an optional second dose (MK0974 300 mg or placebo) to treat a single moderate-to-severe migraine attack
Placebo	Placebo; one orally-administered dose, plus an optional second dose (placebo) to treat a single moderate-to-severe migraine attack

Measured Values

	MK0974 50 mg	MK0974 150 mg	MK0974 300 mg	Placebo
Number of Participants Analyzed [units: participants]	**176**	**380**	**369**	**365**
Number of Patients Reporting Absence of Phonophobia at 2 Hours Post Dose [units: Participants]	**85**	**192**	**206**	**152**

Statistical Analysis 1 for Number of Patients Reporting Absence of Phonophobia at 2 Hours Post Dose

Groups [1]	MK0974 150 mg vs. Placebo
Method [2]	Regression, Logistic
P Value [3]	<0.001

[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:
	P-value constructed using a logistic model adjusting for baseline severity (moderate, severe), region (US, ex-US), treatment and age (continuous).
[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.

Statistical Analysis 2 for Number of Patients Reporting Absence of Phonophobia at 2 Hours Post Dose

Groups [1]	MK0974 300 mg vs. Placebo
Method [2]	Regression, Logistic
P Value [3]	<0.001

[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:
	P-value constructed using a logistic model adjusting for baseline severity (moderate, severe), region (US, ex-US), treatment and age (continuous).
[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.

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

Measure Type	Primary
Measure Title	Number of Patients Reporting Absence of Nausea at 2 Hours Post Dose
Measure Description	Respective experience (yes/no) of migraine-associated symptoms (including nausea) was recorded by the patient in a diary.
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.
All randomized, treated patients who have at least one post-dose measurement at or prior to 2 hours.

Reporting Groups

	Description
MK0974 50 mg	MK0974 50 mg; one orally-administered dose, plus an optional second dose (MK0974 50 mg) to treat a single moderate-to-severe migraine attack
MK0974 150 mg	MK0974 150 mg; one orally-administered dose, plus an optional second dose (MK0974 150 mg) to treat a single moderate-to-severe migraine attack
MK0974 300 mg	MK0974 300 mg; one orally-administered dose, plus an optional second dose (MK0974 300 mg or placebo) to treat a single moderate-to-severe migraine attack
Placebo	Placebo; one orally-administered dose, plus an optional second dose (placebo) to treat a single moderate-to-severe migraine attack

Measured Values

	MK0974 50 mg	**MK0974 150 mg**	**MK0974 300 mg**	**Placebo**
Number of Participants Analyzed [units: participants]	**176**	**380**	**369**	**365**
Number of Patients Reporting Absence of Nausea at 2 Hours Post Dose [units: Participants]	**113**	**260**	**258**	**196**

Statistical Analysis 1 for Number of Patients Reporting Absence of Nausea at 2 Hours Post Dose

Groups [1]	MK0974 150 mg vs. Placebo
Method [2]	Regression, Logistic
P Value [3]	<0.001

[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:
	P-value constructed using a logistic model adjusting for baseline severity (moderate, severe), region (US, ex-US), treatment and age

	(continuous).
[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.

Statistical Analysis 2 for Number of Patients Reporting Absence of Nausea at 2 Hours Post Dose

Groups [1]	MK0974 300 mg vs. Placebo
Method [2]	Regression, Logistic
P Value [3]	<0.001

[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:
	P-value constructed using a logistic model adjusting for baseline severity (moderate, severe), region (US, ex-US), treatment and age (continuous).
[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.

6. Secondary: Number of Patients Who Have Sustained Pain-Freedom From 2 to 24 Hours Postdose [Time Frame: 2 to 24 hours postdose]

Measure Type	Secondary
Measure Title	Number of Patients Who Have Sustained Pain-Freedom From 2 to 24 Hours Postdose
Measure Description	Pain Freedom at 2 hours postdose, with no administration of any rescue medication and no occurrence thereafter of a mild/moderate/severe headache during the 24 hours after dosing with study medication.
Time Frame	2 to 24 hours postdose
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, treated patients who have at least one post-dose measurement at or prior to 2 hours and who either 1) did not have pain freedom at any time between 2 and 24 hours postdose, 2) used rescue medication between 2 and 24 hours postdose or 3) answered the 24 hour recurrence question (a question that ascertains recurrence of migraine pain)

Reporting Groups

	Description
MK0974 50 mg	MK0974 50 mg; one orally-administered dose, plus an optional second dose (MK0974 50 mg) to treat a single moderate-to-severe migraine attack
MK0974 150 mg	MK0974 150 mg; one orally-administered dose, plus an optional second dose (MK0974 150 mg) to treat a single moderate-to-severe migraine attack
MK0974 300 mg	MK0974 300 mg; one orally-administered dose, plus an optional second dose (MK0974 300 mg or placebo) to treat a single moderate-to-severe migraine attack

Placebo	Placebo; one orally-administered dose, plus an optional second dose (placebo) to treat a single moderate-to-severe migraine attack

Measured Values

	MK0974 50 mg	MK0974 150 mg	MK0974 300 mg	Placebo
Number of Participants Analyzed [units: participants]	**177**	**378**	**365**	**363**
Number of Patients Who Have Sustained Pain-Freedom From 2 to 24 Hours Postdose [units: Participants]	**25**	**62**	**63**	**26**

Statistical Analysis 1 for Number of Patients Who Have Sustained Pain-Freedom From 2 to 24 Hours Postdose

Groups [1]	MK0974 150 mg vs. Placebo
Method [2]	Regression, Logistic
P Value [3]	<0.001

[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:
	P-value constructed using a logistic model adjusting for baseline severity (moderate, severe), region (US, ex-US), treatment and age (continuous).
[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.

Statistical Analysis 2 for Number of Patients Who Have Sustained Pain-Freedom From 2 to 24 Hours Postdose

Groups [1]	MK0974 300 mg vs. Placebo
Method [2]	Regression, Logistic
P Value [3]	<0.001

[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:
	P-value constructed using a logistic model adjusting for baseline severity (moderate, severe), region (US, ex-US), treatment and age (continuous).
[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.

7. Secondary: Number of Patients Who Have Total Migraine Freedom 2 to 24 Hours Postdose [Time Frame: 2 to 24 hours postdose]

Measure Type	Secondary
Measure Title	Number of Patients Who Have Total Migraine Freedom 2 to 24 Hours Postdose
Measure Description	Pain Freedom and no migraine-associated symptoms at 2 hours postdose, with no administration of any rescue medication and no occurrence thereafter of a mild/moderate/severe headache or migraine-associated symptom during the 24 hours after dosing with study medication.
Time Frame	2 to 24 hours postdose
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, treated patients who have at least one post-dose measurement at or prior to 2 hours and who either 1) did not have pain freedom at any time between 2 and 24 hours postdose, 2) used rescue medication between 2 and 24 hours postdose or 3) answered the 24 hour recurrence question (a question that ascertains recurrence of migraine pain)

Reporting Groups

	Description
MK0974 50 mg	MK0974 50 mg; one orally-administered dose, plus an optional second dose (MK0974 50 mg) to treat a single moderate-to-severe migraine attack
MK0974 150 mg	MK0974 150 mg; one orally-administered dose, plus an optional second dose (MK0974 150 mg) to treat a single moderate-to-severe migraine attack
MK0974 300 mg	MK0974 300 mg; one orally-administered dose, plus an optional second dose (MK0974 300 mg or placebo) to treat a single moderate-to-severe migraine attack
Placebo	Placebo; one orally-administered dose, plus an optional second dose (placebo) to treat a single moderate-to-severe migraine attack

Measured Values

	MK0974 50 mg	**MK0974 150 mg**	**MK0974 300 mg**	**Placebo**
Number of Participants Analyzed [units: participants]	**177**	**378**	**365**	**363**
Number of Patients Who Have Total Migraine Freedom 2 to 24 Hours Postdose [units: Participants]	**20**	**55**	**54**	**23**

Statistical Analysis 1 for Number of Patients Who Have Total Migraine Freedom 2 to 24 Hours Postdose

Groups [1]	MK0974 150 mg vs. Placebo
Method [2]	Regression, Logistic
P Value [3]	<0.001

[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:

	P-value constructed using a logistic model adjusting for baseline severity (moderate, severe), region (US, ex-US), treatment and age (continuous).
[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.

Statistical Analysis 2 for Number of Patients Who Have Total Migraine Freedom 2 to 24 Hours Postdose

Groups [1]	MK0974 300 mg vs. Placebo
Method [2]	Regression, Logistic
P Value [3]	<0.001

[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:
	P-value constructed using a logistic model adjusting for baseline severity (moderate, severe), region (US, ex-US), treatment and age (continuous).
[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.

8. Secondary: Number of Patients Who Have Total Migraine Freedom 2 Hours Postdose [Time Frame: 2 hours postdose]

Measure Type	Secondary
Measure Title	Number of Patients Who Have Total Migraine Freedom 2 Hours Postdose
Measure Description	Pain Freedom and no migraine-associated symptoms at 2 hours postdose.
Time Frame	2 hours postdose
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, treated patients who have at least one post-dose measurement at or prior to 2 hours.

Reporting Groups

	Description
MK0974 50 mg	MK0974 50 mg; one orally-administered dose, plus an optional second dose (MK0974 50 mg) to treat a single moderate-to-severe migraine attack
MK0974 150 mg	MK0974 150 mg; one orally-administered dose, plus an optional second dose (MK0974 150 mg) to treat a single moderate-to-severe migraine attack
MK0974 300 mg	MK0974 300 mg; one orally-administered dose, plus an optional second dose (MK0974 300 mg or placebo) to treat a single moderate-to-severe migraine attack
Placebo	Placebo; one orally-administered dose, plus an optional second dose (placebo) to treat a single moderate-to-severe migraine

	attack

Measured Values

	MK0974 50 mg	MK0974 150 mg	MK0974 300 mg	Placebo
Number of Participants Analyzed [units: participants]	**176**	**380**	**369**	**365**
Number of Patients Who Have Total Migraine Freedom 2 Hours Postdose [units: Participants]	**24**	**78**	**78**	**36**

Statistical Analysis 1 for Number of Patients Who Have Total Migraine Freedom 2 Hours Postdose

Groups [1]	MK0974 150 mg vs. Placebo
Method [2]	Regression, Logistic
P Value [3]	<0.001

[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:
	P-value constructed using a logistic model adjusting for baseline severity (moderate, severe), region (US, ex-US), treatment and age (continuous).
[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.

Statistical Analysis 2 for Number of Patients Who Have Total Migraine Freedom 2 Hours Postdose

Groups [1]	MK0974 300 mg vs. Placebo
Method [2]	Regression, Logistic
P Value [3]	<0.001

[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:
	P-value constructed using a logistic model adjusting for baseline severity (moderate, severe), region (US, ex-US), treatment and age (continuous).
[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.

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Adverse events were recorded from the time that the patient was first treated with study therapy through 14 days following the last dose of study therapy.
Additional Description	Subjective adverse experiences were recorded by the patient in a paper diary. Patients were counted in the treatment group for which they actually took study drug. One patient gave some of their study drug to another patient; resulting in the difference in 2 groups of 1 from what was reported in the Participant Flow "Completed--With Data".

Reporting Groups

	Description
MK0974 50 mg	MK0974 50 mg; one orally-administered dose, plus an optional second dose (MK0974 50 mg) to treat a single moderate-to-severe migraine attack
MK0974 150 mg	MK0974 150 mg; one orally-administered dose, plus an optional second dose (MK0974 150 mg) to treat a single moderate-to-severe migraine attack
MK0974 300 mg	MK0974 300 mg; one orally-administered dose, plus an optional second dose (MK0974 300 mg or placebo) to treat a single moderate-to-severe migraine attack
Placebo	Placebo; one orally-administered dose, plus an optional second dose (placebo) to treat a single moderate-to-severe migraine attack

Serious Adverse Events

	MK0974 50 mg	MK0974 150 mg	MK0974 300 mg	Placebo
Total, serious adverse events				
# participants affected / at risk	**0/177 (0.00%)**	**1/381 (0.26%)**	**0/370 (0.00%)**	**1/366 (0.27%)**
Injury, poisoning and procedural complications				
Traumatic Brain Injury [*1]				
# participants affected / at risk	**0/177 (0.00%)**	**0/381 (0.00%)**	**0/370 (0.00%)**	**1/366 (0.27%)**
Vascular disorders				
Hypertension [*1]				
# participants affected / at risk	**0/177 (0.00%)**	**1/381 (0.26%)**	**0/370 (0.00%)**	**0/366 (0.00%)**

* Events were collected by non-systematic assessment

1 Term from vocabulary, MedDRA (10.1)

Other Adverse Events

Hide Other Adverse Events

Time Frame	Adverse events were recorded from the time that the patient was first treated with study therapy through 14 days following the last dose of study therapy.
Additional Description	Subjective adverse experiences were recorded by the patient in a paper diary. Patients were counted in the treatment group for which they actually took study drug. One patient gave some of their study drug to another patient; resulting in the difference in 2 groups of 1 from what was reported in the Participant Flow "Completed--With Data".

Frequency Threshold

Threshold above which other adverse events are reported	2%

Reporting Groups

	Description
MK0974 50 mg	MK0974 50 mg; one orally-administered dose, plus an optional second dose (MK0974 50 mg) to treat a single moderate-to-severe migraine attack
MK0974 150 mg	MK0974 150 mg; one orally-administered dose, plus an optional second dose (MK0974 150 mg) to treat a single moderate-to-severe migraine attack
MK0974 300 mg	MK0974 300 mg; one orally-administered dose, plus an optional second dose (MK0974 300 mg or placebo) to treat a single moderate-to-severe migraine attack
Placebo	Placebo; one orally-administered dose, plus an optional second dose (placebo) to treat a single moderate-to-severe migraine attack

Other Adverse Events

	MK0974 50 mg	MK0974 150 mg	MK0974 300 mg	Placebo
Total, other (not including serious) adverse events				
# participants affected / at risk	**45/177 (25.42%)**	**69/381 (18.11%)**	**94/370 (25.41%)**	**77/366 (21.04%)**
Ear and labyrinth disorders				
Vertigo * 1				
# participants affected / at risk	**3/177 (1.69%)**	**2/381 (0.52%)**	**5/370 (1.35%)**	**10/366 (2.73%)**
Gastrointestinal disorders				
Abdominal Pain Upper * 1				
# participants affected / at risk	**2/177 (1.13%)**	**4/381 (1.05%)**	**12/370 (3.24%)**	**6/366 (1.64%)**
Dry Mouth * 1				
# participants affected / at risk	**9/177 (5.08%)**	**17/381 (4.46%)**	**19/370 (5.14%)**	**19/366 (5.19%)**
Nausea * 1				
# participants affected / at risk	**14/177 (7.91%)**	**13/381 (3.41%)**	**19/370 (5.14%)**	**20/366 (5.46%)**
Vomiting * 1				
# participants affected / at risk	**6/177 (3.39%)**	**3/381 (0.79%)**	**6/370 (1.62%)**	**10/366 (2.73%)**
General disorders				
Fatigue * 1				
# participants affected / at risk	**9/177 (5.08%)**	**15/381 (3.94%)**	**25/370 (6.76%)**	**14/366 (3.83%)**
Nervous system disorders				
Dizziness * 1				
# participants affected / at risk	**13/177 (7.34%)**	**9/381 (2.36%)**	**20/370 (5.41%)**	**12/366 (3.28%)**
Headache * 1				
# participants affected / at risk	**0/177 (0.00%)**	**3/381 (0.79%)**	**3/370 (0.81%)**	**8/366 (2.19%)**
Paraesthesia * 1				
# participants affected / at risk	**3/177 (1.69%)**	**5/381 (1.31%)**	**8/370 (2.16%)**	**9/366 (2.46%)**

Somnolence * 1				
# participants affected / at risk	**7/177 (3.95%)**	**14/381 (3.67%)**	**10/370 (2.70%)**	**11/366 (3.01%)**

* Events were collected by non-systematic assessment
1 Term from vocabulary, MedDRA (10.1)

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data

No text entered.

More Information

Hide More Information

Certain Agreements:

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

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

The agreement is:

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

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

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

Restriction Description: Merck agreements may vary with individual investigators, but will not prohibit any investigator from publishing. Merck supports the publication of results from all centers of a multi-center trial but requests that reports based on single-site data not precede the primary publication of the entire clinical trial.

Results Point of Contact:

Name/Title: Senior Vice President, Global Clinical Development
Organization: Merck Sharp & Dohme Corp
phone: 1-800-672-6372
e-mail: ClinicalTrialDisclosure@merck.com

Publications of Results:

Connor KM, Shapiro RE, Diener HC, Lucas S, Kost J, Fan X, Fei K, Assaid C, Lines C, Ho TW. Randomized, controlled trial of telcagepant for the acute treatment of migraine. Neurology. 2009 Sep 22;73(12):970-7. doi: 10.1212/WNL.0b013e3181b87942.

Responsible Party: Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier: NCT00432237 History of Changes
Other Study ID Numbers: 0974-016
2006_526
Study First Received: February 5, 2007
Results First Received: July 19, 2010

Last Updated:	June 8, 2015
Health Authority:	United States: Food and Drug Administration

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