A Study of Rizatriptan for the Treatment of Acute Migraine in Patients on Topiramate for Migraine Prophylaxis

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00812006

First received: December 17, 2008
Last updated: February 13, 2015
Last verified: February 2015
History of Changes

Purpose

This study will provide additional efficacy data for rizatriptan when used for an acute migraine attack in patients already taking topiramate for migraine prophylaxis.

Condition	Intervention	Phase
Migraine	Drug: rizatriptan benzoate Drug: Comparator: placebo	Phase 3

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

Official Title: A Multicenter, Randomized, Double-Blind, Placebo-Controlled Crossover Trial to Evaluate the Efficacy and Tolerability of Rizatriptan 10 mg ODT for the Treatment of Acute Migraine in Patients on Topiramate for Migraine Prophylaxis

Resource links provided by NLM:

MedlinePlus related topics: Migraine

Drug Information available for: Rizatriptan Rizatriptan benzoate

U.S. FDA Resources

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

Primary Outcome Measures:

- Pain Relief (PR) [Time Frame: 2 hours post dose] [Designated as safety issue: No]

  Pain severity was rated by the participants in a paper diary. Pain severity rating scale : 0 (no pain), 1 (mild pain), 2 (moderate pain), or 3 (severe pain). Pain relief (PR) is defined as a reduction in headache severity from Grade 3/2 at baseline to Grade 1/0 post dose.

Secondary Outcome Measures:

- Sustained Pain Relief (SPR) [Time Frame: 2 - 24 hours post dose] [Designated as safety issue: No]

  24-hour sustained pain relief (defined as pain relief at 2 hours post dose, with no administration of any rescue medication and with no occurrence of a moderate/severe headache during the respective period after dosing with the blinded study medication.

- Pain Freedom (PF) [Time Frame: 2 hours post dose] [Designated as safety issue: No]

  Headache pain severity, relative to the administration of study medication, was rated by the participants in a paper diary. Pain severity rating scale: 0 (no pain), 1 (mild pain), 2 (moderate pain), or 3 (severe pain). Pain freedom (PF) is defined as a reduction in headache severity from Grade 3/2 at baseline to Grade 0 (no pain) post dose.

- Normal Rating of Functional Disability (NRFD) [Time Frame: 2 hours post dose] [Designated as safety issue: No]

  Level of functional disability was assessed on a paper diary by the participants. Level of functional disability was rated as: normal, mildly impaired, severely impaired, or unable to do activities, requires bedrest. Functional disability ratings was dichotomized to Normal and Not Normal (mildly impaired, severely impaired, or unable to do activities, requires bedrest) for analysis.

- Treatment Satisfaction (TS) [Time Frame: 24 hours post dose] [Designated as safety issue: No]

  Patient satisfaction was assessed on a paper diary by the participants. Level of satisfaction was rated as: completely satisfied, very satisfied, somewhat satisfied, neither satisfied nor dissatisfied, somewhat dissatisfied, very dissatisfied, or completely dissatisfied. The overall 24-hour assessment of study medication was dichotomized to Satisfaction (completely satisfied, very satisfied, somewhat satisfied) and Non-satisfaction (neither satisfied nor dissatisfied, somewhat dissatisfied, very dissatisfied, or completely dissatisfied) for analysis.

Enrollment:	108
Study Start Date:	March 2009
Study Completion Date:	October 2009
Primary Completion Date:	October 2009 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: A Treatment Sequence A: rizatriptan, rizatriptan, placebo	Drug: rizatriptan benzoate rizatriptan 10 mg Orally Disintegrating Tablet (ODT) orally for a moderate or severe migraine attack Other Name: Maxalt Drug: Comparator: placebo Placebo to rizatriptan 10 mg ODT orally for a moderate or severe migraine attack
Experimental: B Sequence B: rizatriptan, placebo, rizatriptan	Drug: rizatriptan benzoate rizatriptan 10 mg Orally Disintegrating Tablet (ODT) orally for a moderate or severe migraine attack Other Name: Maxalt Drug: Comparator: placebo Placebo to rizatriptan 10 mg ODT orally for a moderate or severe migraine attack
Experimental: C Sequence C: placebo, rizatriptan, rizatriptan	Drug: rizatriptan benzoate rizatriptan 10 mg Orally Disintegrating Tablet (ODT) orally for a moderate or severe migraine attack Other Name: Maxalt Drug: Comparator: placebo Placebo to rizatriptan 10 mg ODT orally for a moderate or severe migraine attack

Eligibility

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

Criteria

Inclusion Criteria:

- Patient has a history of migraine with or without aura for more than one year, with between 2 and 8 moderate to severe attacks per month
- Patient is currently taking at least 50 mg topiramate daily for migraine prophylaxis
- Patient can distinguish between migraine and other types of headache
- Patient agrees to remain abstinent or use effective birth control during the study

Exclusion Criteria:

- Patient is pregnant or breast-feeding
- Patient has a history of mostly mild migraines or migraines that resolve within 2 hours
- Patient has more than 15 headache-days per month or has taken medication for acute headache on more than 10 days per month in the 3 months prior to screening.
- Patient was > 50 years old at age of migraine onset
- Patient has history of heart disease
- Patient has uncontrolled hypertension
- Patient has had cancer within 5 years of screening (excepting certain skin and cervical cancers)
- Patient has started taking Selective Serotonin Reuptake Inhibitors (SSRIs) or Serotonin-Norepinephrine Reuptake Inhibitors (SNRIs) or has changed doses within 3 months of screening
- Patient is taking more than one other migraine prophylactic medication
- Patient has repeatedly failed to respond to or tolerate rizatriptan

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: NCT00812006

Sponsors and Collaborators

Merck Sharp & Dohme Corp.

Investigators

Study Director: Medical Monitor Merck Sharp & Dohme Corp.

More Information

Additional Information:

MedWatch - FDA maintained medical product safety Information EXIT

Merck: Patient & Caregiver U.S. Product Web Site EXIT

Publications:

Seeburger JL, Cady RK, Winner P, MacGregor A, Valade D, Ge Y, Zhang Y, Hustad CM, Strickler N, Schaefer E, Connor KM, Ho TW. Rizatriptan for treatment of acute migraine in patients taking topiramate for migraine prophylaxis. Headache. 2012 Jan;52(1):57-67. doi: 10.1111/j.1526-4610.2011.02027.x. Epub 2011 Nov 11.

Responsible Party: Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier: NCT00812006 History of Changes

Other Study ID Numbers:	0462-085 2008_597
Study First Received:	December 17, 2008
Results First Received:	September 23, 2010
Last Updated:	February 13, 2015
Health Authority:	United States: Food and Drug Administration

Additional relevant MeSH terms:

- Migraine Disorders
- Brain Diseases
- Central Nervous System Diseases
- Headache Disorders
- Headache Disorders, Primary
- Nervous System Diseases
- Rizatriptan
- Molecular Mechanisms of Pharmacological Action
- Neurotransmitter Agents
- Pharmacologic Actions
- Physiological Effects of Drugs
- Serotonin Agents
- Serotonin Receptor Agonists

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Results First Received: September 23, 2010

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Efficacy Study; Intervention Model: Crossover Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Treatment
Condition:	Migraine
Interventions:	Drug: rizatriptan benzoate 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

First Patient In: 26 March 2009; Last Patient Last Visit: 22 October 2009.

17 Outpatient centers worldwide (10 United States; 2 Canada; 2 Spain, 2 Italy; 1 France)

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 the same visit.

Reporting Groups

	Description
Rizatriptan / Rizatriptan / Placebo	First migraine treated with Rizatriptan 10 mg Orally Disintegrating Tablet (ODT); second migraine treated with Rizatriptan 10 mg Orally Disintegrating Tablet (ODT); third migraine treated with Placebo
Rizatriptan / Placebo / Rizatriptan	First migraine treated with Rizatriptan 10 mg Orally Disintegrating Tablet (ODT); second migraine treated with Placebo; third migraine treated with Rizatriptan 10 mg Orally Disintegrating Tablet (ODT)
Placebo / Rizatriptan / Rizatriptan	First migraine treated with Placebo; second migraine treated with Rizatriptan 10 mg Orally Disintegrating Tablet (ODT); third migraine treated with Rizatriptan 10 mg Orally Disintegrating Tablet (ODT)

Participant Flow: Overall Study

	Rizatriptan / Rizatriptan / Placebo	Rizatriptan / Placebo / Rizatriptan	Placebo / Rizatriptan / Rizatriptan
STARTED	**36**	**36**	**36**
COMPLETED	**30**	**33**	**30**
NOT COMPLETED	**6**	**3**	**6**
Lost to Follow-up	**0**	**0**	**2**
Physician Decision	**0**	**0**	**1**
Withdrawal by Subject	**2**	**1**	**1**
Lack of Qualifying Event	**4**	**2**	**2**

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
Rizatriptan / Rizatriptan / Placebo	First migraine treated with Rizatriptan 10 mg Orally Disintegrating Tablet (ODT); second migraine treated with Rizatriptan 10 mg Orally Disintegrating Tablet (ODT); third migraine treated with Placebo
Rizatriptan / Placebo / Rizatriptan	First migraine treated with Rizatriptan 10 mg Orally Disintegrating Tablet (ODT); second migraine treated with Placebo; third migraine treated with Rizatriptan 10 mg Orally Disintegrating Tablet (ODT)
Placebo / Rizatriptan / Rizatriptan	First migraine treated with Placebo; second migraine treated with Rizatriptan 10 mg Orally Disintegrating Tablet (ODT); third migraine treated with Rizatriptan 10 mg Orally Disintegrating Tablet (ODT)
Total	Total of all reporting groups

Baseline Measures

	Rizatriptan / Rizatriptan / Placebo	Rizatriptan / Placebo / Rizatriptan	Placebo / Rizatriptan / Rizatriptan	Total
Number of Participants	**36**	**36**	**36**	**108**

[units: participants]				
Age [units: years] Mean (Standard Deviation)	**48.3 (12.0)**	**43.9 (10.8)**	**40.0 (11.6)**	**44.0 (11.9)**
Gender [units: participants]				
Female	**32**	**33**	**34**	**99**
Male	**4**	**3**	**2**	**9**
Ethnicity Origin [units: participants]				
Black	**0**	**1**	**0**	**1**
White	**36**	**35**	**36**	**107**
Racial Origin [units: participants]				
Hispanic or Latino	**11**	**9**	**10**	**30**
Not Hispanic or Latino	**25**	**27**	**26**	**78**

Outcome Measures

Hide All Outcome Measures

1. Primary: Pain Relief (PR) [Time Frame: 2 hours post dose]

Measure Type	Primary
Measure Title	Pain Relief (PR)
Measure Description	Pain severity was rated by the participants in a paper diary. Pain severity rating scale : 0 (no pain), 1 (mild pain), 2 (moderate pain), or 3 (severe pain). Pain relief (PR) is defined as a reduction in headache severity from Grade 3/2 at baseline to Grade 1/0 post dose.
Time Frame	2 hours post dose
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set, which included all randomized participants who had at least one evaluable attack. To be considered an evaluable attack, the participant must have administered study treatment for this attack and have both a baseline severity measurement and at least one post-dose efficacy measurement at or prior to the 2-hour time point.

Reporting Groups

	Description
Rizatriptan	Rizatriptan 10 mg. Patients who treated at least one attack, that was intended to be treated with rizatriptan 10 mg (excluding sponsor-provided rescue), were included. Although a patient may have treated twice with rizatriptan 10 mg, the patient was counted only once for the rizatriptan group.
Placebo	Placebo. Patients who treated one attack, that was intended to be treated with placebo, were included. One patient who treated an attack with placebo within 48 hours of the previous attack was excluded from the placebo group.

Measured Values

	Rizatriptan	Placebo
Number of Participants Analyzed [units: participants]	**99**	**93**
Pain Relief (PR) [units: Attacks]		
Resulting in PR at 2 hours post dose	**105**	**21**
Not resulting in PR at 2 hours post dose	**88**	**72**

Statistical Analysis 1 for Pain Relief (PR)

Groups [1]	All groups
Method [2]	Generalized Linear Mixed Model
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:
	An unstructured covariance matrix was used to model the correlation among repeated measurements within a patient.
[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. Secondary: Sustained Pain Relief (SPR) [Time Frame: 2 - 24 hours post dose]

Measure Type	Secondary
Measure Title	Sustained Pain Relief (SPR)
Measure Description	24-hour sustained pain relief (defined as pain relief at 2 hours post dose, with no administration of any rescue medication and with no occurrence of a moderate/severe headache during the respective period after dosing with the blinded study medication.
Time Frame	2 - 24 hours post dose
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set, which included all randomized participants who had at least one evaluable attack. To be considered an evaluable attack, the attack must have met the FAS criteria for PR at 2 hours post-dose, and from 2-24 hours the participant either answered 24-hour headache recurrence question or didn't have PR at any time or took rescue.

Reporting Groups

	Description
Rizatriptan	Rizatriptan 10 mg. Patients who treated at least one attack, that was intended to be treated with rizatriptan 10 mg (excluding sponsor-provided rescue), were included. Although a patient may have treated twice with rizatriptan 10 mg, the patient was counted only once for the rizatriptan group.
Placebo	Placebo. Patients who treated one attack, that was intended to be treated with placebo, were included. One patient who treated an attack with placebo within 48 hours of the previous attack was excluded from the placebo group.

Measured Values

	Rizatriptan	Placebo
Number of Participants Analyzed [units: participants]	**99**	**93**
Sustained Pain Relief (SPR) [units: Attacks]		
Resulting in SPR 2-24 hours post dose	**67**	**12**
Not resulting in SPR 2-24 hours post dose	**126**	**81**

Statistical Analysis 1 for Sustained Pain Relief (SPR)

Groups [1]	All groups
Method [2]	Generalized Linear Mixed Model
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:
	A compound-symmetry covariance matrix was used to model the correlation among repeated measurements within a patient, due to a convergence issue.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Nominal p-value was adjusted under Benjamini and Hochberg's false discovery rate procedure for the multiple secondary endpoints at α=0.1 significance level.

3. Secondary: Pain Freedom (PF) [Time Frame: 2 hours post dose]

Measure Type	Secondary
Measure Title	Pain Freedom (PF)
Measure Description	Headache pain severity, relative to the administration of study medication, was rated by the participants in a paper diary. Pain severity rating scale: 0 (no pain), 1 (mild pain), 2 (moderate pain), or 3 (severe pain). Pain freedom (PF) is defined as a reduction in headache severity from Grade 3/2 at baseline to Grade 0 (no pain) post dose.
Time Frame	2 hours post dose
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set, which included all randomized participants who had at least one evaluable attack. To be considered an evaluable attack, the participant must have administered study treatment for this attack and have both a baseline severity measurement and at least one post-dose efficacy measurement at or prior to the 2-hour time point.

Reporting Groups

	Description
Rizatriptan	Rizatriptan 10 mg. Patients who treated at least one attack, that was intended to be treated with rizatriptan 10 mg (excluding sponsor-provided rescue), were included. Although a patient may have treated twice with rizatriptan 10 mg, the patient was counted only once for the rizatriptan group.
Placebo	Placebo. Patients who treated one attack, that was intended to be treated with placebo, were included. One patient who treated an attack with placebo within 48 hours of the previous attack was excluded from the placebo group.

Measured Values

	Rizatriptan	**Placebo**
Number of Participants Analyzed [units: participants]	**99**	**93**
Pain Freedom (PF) [units: Attacks]		
Resulting in PF 2 hours post dose	**74**	**9**
Not resulting in PF 2 hours post dose	**119**	**84**

Statistical Analysis 1 for Pain Freedom (PF)

Groups [1]	All groups
Method [2]	Generalized Linear Mixed Model
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:
	An unstructured covariance matrix was used to model the correlation among repeated measurements within a patient.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Nominal p-value was adjusted under Benjamini and Hochberg's false discovery rate procedure for the multiple secondary endpoints at α=0.1 significance level.

4. Secondary: Normal Rating of Functional Disability (NRFD) [Time Frame: 2 hours post dose]

Measure Type	Secondary

Measure Title	Normal Rating of Functional Disability (NRFD)
Measure Description	Level of functional disability was assessed on a paper diary by the participants. Level of functional disability was rated as: normal, mildly impaired, severely impaired, or unable to do activities, requires bedrest. Functional disability ratings was dichotomized to Normal and Not Normal (mildly impaired, severely impaired, or unable to do activities, requires bedrest) for analysis.
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.
Full Analysis Set, which included all randomized participants who had at least one evaluable attack. To be considered an evaluable attack, the participant must have administered study treatment for this attack and have both a baseline severity measurement and at least one post-dose efficacy measurement at or prior to the 2-hour time point.

Reporting Groups

	Description
Rizatriptan	Rizatriptan 10 mg. Patients who treated at least one attack, that was intended to be treated with rizatriptan 10 mg (excluding sponsor-provided rescue), were included. Although a patient may have treated twice with rizatriptan 10 mg, the patient was counted only once for the rizatriptan group.
Placebo	Placebo. Patients who treated one attack, that was intended to be treated with placebo, were included. One patient who treated an attack with placebo within 48 hours of the previous attack was excluded from the placebo group.

Measured Values

	Rizatriptan	**Placebo**
Number of Participants Analyzed [units: participants]	**99**	**93**
Normal Rating of Functional Disability (NRFD) [units: Attacks]		
Resulting in NRFD at 2 hours post dose	**85**	**16**
Not resulting in NRFD at 2 hours post dose	**108**	**77**

Statistical Analysis 1 for Normal Rating of Functional Disability (NRFD)

Groups [1]	All groups
Method [2]	Generalized Linear Mixed Model
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:
	An unstructured covariance matrix was used to model the correlation among repeated measurements within a patient.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:

Nominal p-value was adjusted under Benjamini and Hochberg's falsediscovery rate procedure for the multiple secondary endpoints at α=0.1 significance level.

5. Secondary: Treatment Satisfaction (TS) [Time Frame: 24 hours post dose]

Measure Type	Secondary
Measure Title	Treatment Satisfaction (TS)
Measure Description	Patient satisfaction was assessed on a paper diary by the participants. Level of satisfaction was rated as: completely satisfied, very satisfied, somewhat satisfied, neither satisfied nor dissatisfied, somewhat dissatisfied, very dissatisfied, or completely dissatisfied. The overall 24-hour assessment of study medication was dichotomized to Satisfaction (completely satisfied, very satisfied, somewhat satisfied) and Non-satisfaction (neither satisfied nor dissatisfied, somewhat dissatisfied, very dissatisfied, or completely dissatisfied) for analysis.
Time Frame	24 hours post dose
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set, which included all randomized participants who had at least one evaluable attack. To be considered an evaluable attack, the participant must have administered study treatment for this attack and have both a baseline severity measurement and post-dose satisfaction measurement at the 24-hour time point.

Reporting Groups

	Description
Rizatriptan	Rizatriptan 10 mg. Patients who treated at least one attack, that was intended to be treated with rizatriptan 10 mg (excluding sponsor-provided rescue), were included. Although a patient may have treated twice with rizatriptan 10 mg, the patient was counted only once for the rizatriptan group.
Placebo	Placebo. Patients who treated one attack, that was intended to be treated with placebo, were included. One patient who treated an attack with placebo within 48 hours of the previous attack was excluded from the placebo group.

Measured Values

	Rizatriptan	**Placebo**
Number of Participants Analyzed [units: participants]	**99**	**93**
Treatment Satisfaction (TS) [units: Attacks]		
Resulting in TS at 24 hours post dose	**117**	**31**
Not resulting in TS at 24 hours post dose	**76**	**62**

Statistical Analysis 1 for Treatment Satisfaction (TS)

Groups [1]	All groups
Method [2]	Generalized Linear Mixed Model

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:
	A compound-symmetry covariance matrix was used to model the correlation among repeated measurements within a patient, due to a convergence issue.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Nominal p-value was adjusted under Benjamini and Hochberg's false discovery rate procedure for the multiple secondary endpoints at α=0.1 significance level.

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Adverse experiences were collected up to 14 days after each qualified migraine headache attack that was treated with study medication.
Additional Description	Adverse experiences were reported by the patient on a paper diary. Adverse events occurring within 14 days of administration of rizatriptan (including sponsor-provided rescue) are attributed to rizatriptan group, even if placebo was administered more recently

Reporting Groups

	Description
Rizatriptan	Rizatriptan 10 mg. Patients who treated at least one attack with rizatriptan 10 mg (including sponsor-provided rescue) were included. Although a patient may have treated twice with rizatriptan 10 mg, the patient was counted only once for the rizatriptan group. Adverse events occurring within 14 days of any administration of rizatriptan (including sponsor-provided rescue) were attributed to rizatriptan group, even if placebo was administered more recently. It is possible for one patient to be counted twice (once in each treatment group). The number of randomized patients is 108, out of which, 101 took at least one dose of rizatriptan (including sponsor-provided rescue), and 94 took placebo.
Placebo	Placebo. Patients who treated an attack with placebo were included. Adverse events occurring within 14 days of administration of placebo, but not within 14 days of any administration of rizatriptan (including sponsor-provided rescue), were attributed to placebo group. It is possible for one patient to be counted twice (once in each treatment group). The number of randomized patients is 108, out of which, 101 took at least one dose of rizatriptan (including sponsor-provided rescue), and 94 took placebo.

Serious Adverse Events

	Rizatriptan	Placebo
Total, serious adverse events		
# participants affected / at risk	**0/101 (0.00%)**	**0/94 (0.00%)**

Other Adverse Events

Hide Other Adverse Events

Time Frame	Adverse experiences were collected up to 14 days after each qualified migraine headache attack that was treated with study medication.
Additional Description	Adverse experiences were reported by the patient on a paper diary. Adverse events occurring within 14 days of administration of rizatriptan (including sponsor-provided rescue) are attributed to rizatriptan group, even if placebo was administered more recently

Frequency Threshold

Threshold above which other adverse events are reported	0%

Reporting Groups

	Description
Rizatriptan	Rizatriptan 10 mg. Patients who treated at least one attack with rizatriptan 10 mg (including sponsor-provided rescue) were included. Although a patient may have treated twice with rizatriptan 10 mg, the patient was counted only once for the rizatriptan group. Adverse events occurring within 14 days of any administration of rizatriptan (including sponsor-provided rescue) were attributed to rizatriptan group, even if placebo was administered more recently. It is possible for one patient to be counted twice (once in each treatment group). The number of randomized patients is 108, out of which, 101 took at least one dose of rizatriptan (including sponsor-provided rescue), and 94 took placebo.
Placebo	Placebo. Patients who treated an attack with placebo were included. Adverse events occurring within 14 days of administration of placebo, but not within 14 days of any administration of rizatriptan (including sponsor-provided rescue), were attributed to placebo group. It is possible for one patient to be counted twice (once in each treatment group). The number of randomized patients is 108, out of which, 101 took at least one dose of rizatriptan (including sponsor-provided rescue), and 94 took placebo.

Other Adverse Events

	Rizatriptan	Placebo
Total, other (not including serious) adverse events		
# participants affected / at risk	**16/101 (15.84%)**	**3/94 (3.19%)**
Gastrointestinal disorders		
Abdominal Distension [*1]		
# participants affected / at risk	**1/101 (0.99%)**	**0/94 (0.00%)**
Abdominal pain upper [*1]		
# participants affected / at risk	**2/101 (1.98%)**	**0/94 (0.00%)**
Diarrhoea [*1]		
# participants affected / at risk	**1/101 (0.99%)**	**0/94 (0.00%)**
Nausea [*1]		
# participants affected / at risk	**2/101 (1.98%)**	**1/94 (1.06%)**
General disorders		
Chest discomfort [*1]		

# participants affected / at risk	1/101 (0.99%)	0/94 (0.00%)
Fatigue * 1		
# participants affected / at risk	1/101 (0.99%)	1/94 (1.06%)
Malaise * 1		
# participants affected / at risk	0/101 (0.00%)	1/94 (1.06%)
Temperature intolerance * 1		
# participants affected / at risk	1/101 (0.99%)	0/94 (0.00%)
Immune system disorders		
Seasonal Allergy * 1		
# participants affected / at risk	1/101 (0.99%)	0/94 (0.00%)
Infections and infestations		
Vaginal infection * 1		
# participants affected / at risk	1/101 (0.99%)	0/94 (0.00%)
Injury, poisoning and procedural complications		
Intentional overdose * 1		
# participants affected / at risk	1/101 (0.99%)	0/94 (0.00%)
Musculoskeletal and connective tissue disorders		
Arthalgia * 1		
# participants affected / at risk	1/101 (0.99%)	0/94 (0.00%)
Back pain * 1		
# participants affected / at risk	1/101 (0.99%)	0/94 (0.00%)
Pain in jaw * 1		
# participants affected / at risk	1/101 (0.99%)	0/94 (0.00%)
Nervous system disorders		
Allodynia * 1		
# participants affected / at risk	1/101 (0.99%)	0/94 (0.00%)
Dizziness * 1		
# participants affected / at risk	2/101 (1.98%)	1/94 (1.06%)
Hypersomnia * 1		
# participants affected / at risk	1/101 (0.99%)	0/94 (0.00%)
Hypoaesthesia * 1		
# participants affected / at risk	1/101 (0.99%)	0/94 (0.00%)
Peripheral paralysis * 1		
# participants affected / at risk	1/101 (0.99%)	0/94 (0.00%)
Somnolence * 1		
# participants affected / at risk	6/101 (5.94%)	0/94 (0.00%)
Psychiatric disorders		
Disorientation * 1		
# participants affected / at risk	1/101 (0.99%)	0/94 (0.00%)
Renal and urinary disorders		
Pollakiuria * 1		

# participants affected / at risk	1/101 (0.99%)	0/94 (0.00%)

* Events were collected by non-systematic assessment
1 Term from vocabulary, MedDRA (12.0)

Limitations and Caveats

Hide Limitations and Caveats

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

More Information

Hide More Information

Certain Agreements:

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

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

The agreement is:

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

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

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

Restriction Description: 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: ClinicalTrialsDisclosure@spcorp.com

Publications of Results:

Seeburger JL, Cady RK, Winner P, MacGregor A, Valade D, Ge Y, Zhang Y, Hustad CM, Strickler N, Schaefer E, Connor KM, Ho TW. Rizatriptan for treatment of acute migraine in patients taking topiramate for migraine prophylaxis. Headache. 2012 Jan;52(1):57-67. doi: 10.1111/j.1526-4610.2011.02027.x. Epub 2011 Nov 11.

Responsible Party: Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier: NCT00812006 History of Changes
Other Study ID Numbers: 0462-085
2008_597
Study First Received: December 17, 2008
Results First Received: September 23, 2010

Last Updated:	February 13, 2015
Health Authority:	United States: Food and Drug Administration

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For Patients and Families | **For Researchers** | **For Study Record Managers**

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