Study to Test Rizatriptan in the Early Treatment of Acute Migraine (0462-081)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00516737

First received: August 13, 2007
Last updated: July 21, 2015
Last verified: July 2015
History of Changes

Purpose

The purpose of this study is to test the effectiveness of rizatriptan benzoate in the early treatment of an acute migraine attack.

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

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

Official Title: A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Factorial Design Clinical Trial to Study the Efficacy and Safety of MK0462 / Rizatriptan 10 mg for the Early Treatment of Acute Migraine

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:

- Number of Participants Who Are Pain Free 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. Pain severity rating scale: 0 (no pain), 1 (mild), 2 (moderate), or 3 (severe). Pain free = rating of 0 (no pain) at 2 hours post-dose.

Secondary Outcome Measures:

- Number of Participants With 24-Hour Sustained Pain Freedom [Time Frame: 24 hours post-dose] [Designated as safety issue: No]

  24-hour sustained pain freedom (defined as pain freedom from 2 to 24 hours post-dose and no use of rescue medication). Participants assessed pain severity and use of rescue medication on a paper diary.

- Number of Participants With no Rescue Use up to 24 Hours Post-Dose [Time Frame: 24 hours post-dose] [Designated as safety issue: No]

  Participants recorded use of any rescue medication up to 24 hours after dosing with study medication on a paper diary.

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

  Absence or presence of photophobia was recorded by the participants on a paper diary. Absence is defined as no photophobia at 2 hours post-dose.

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

  Absence or presence of phonophobia was recorded by the participants on a paper diary. Absence is defined as no phonophobia at 2 hours post-dose.

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

  Absence or presence of nausea was recorded by the participants on a paper diary. Absence is defined as no nausea at 2 hours post-dose.

- Number of Participants With Absence of Functional Disability at 2 Hours Post-Dose [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 bed rest. Absence of functional disability defined as a rating of normal at 2 hours post-dose.

Enrollment:	207
Study Start Date:	October 2007
Study Completion Date:	April 2008
Primary Completion Date:	April 2008 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: 1 Active Drug	Drug: Comparator: rizatriptan benzoate Rizatriptan 10 mg Orally Disintegrating Tablet (ODT); one dose, treatment of a single migraine attack Other Name: MK0462
Placebo Comparator: 2 Matching Pbo Comparator	Drug: Comparator: Placebo Matching placebo; one dose, treatment of a single migraine attack

Eligibility

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

Criteria

Inclusion Criteria:

- Greater than one year history of migraine

- Attacks typically mild when they begin and progress to moderate or severe
- Experience 1-4 migraine attacks per month

Exclusion Criteria:

- More than 15 headache days per month
- Heart disease
- Uncontrolled high blood pressure

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: NCT00516737

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:

Cady RK, Martin VT, Géraud G, Rodgers A, Zhang Y, Ho AP, Hustad CM, Ho TP, Connor KM, Ramsey KE. Rizatriptan 10-mg ODT for early treatment of migraine and impact of migraine education on treatment response. Headache. 2009 May;49(5):687-96.

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ClinicalTrials.gov Identifier:	NCT00516737 History of Changes
Other Study ID Numbers:	0462-081 2007_547
Study First Received:	August 13, 2007
Results First Received:	March 12, 2009
Last Updated:	July 21, 2015
Health Authority:	United States: Food and Drug Administration

Additional relevant MeSH terms:

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

ClinicalTrials.gov processed this record on April 13, 2016

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Results First Received: March 12, 2009

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: Comparator: 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
Phase III First Patient In: 03-October-2007 Last Patient Last Visit: 08-April-2008 13 outpatient centers worldwide (10 United States, 3 Germany)

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

Rizatriptan 10 mg ODT	Rizatriptan 10 mg Orally Disintegrating Tablet (ODT); one dose, treatment of a single migraine attack
Placebo	Matching placebo; one dose, treatment of a single migraine attack

Participant Flow: Overall Study

	Rizatriptan 10 mg ODT	Placebo
STARTED	**103**	**104**
COMPLETED	**92**	**96**
NOT COMPLETED	**11**	**8**
Lost to Follow-up	**2**	**0**
Physician Decision	**0**	**1**
Withdrawal by Subject	**0**	**1**
Lack of Qualifying Event	**9**	**6**

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 10 mg ODT	Rizatriptan 10 mg Orally Disintegrating Tablet (ODT); one dose, treatment of a single migraine attack
Placebo	Matching placebo; one dose, treatment of a single migraine attack
Total	Total of all reporting groups

Baseline Measures

	Rizatriptan 10 mg ODT	Placebo	Total
Number of Participants [units: participants]	**103**	**104**	**207**
Age [units: years] Mean (Full Range)	**41 (19 to 69)**	**44 (18 to 66)**	**42.5 (18 to 69)**
Gender [units: participants]			
Female	**90**	**96**	**186**

Male	**13**	**8**	**21**
Race/Ethnicity, Customized [units: participants]			
Black or African American	**4**	**3**	**7**
White	**95**	**100**	**195**
Asian	**2**	**1**	**3**
Multi-Racial	**2**	**0**	**2**

Outcome Measures

Hide All Outcome Measures

1. Primary: Number of Participants Who Are Pain Free at 2 Hours Post-Dose [Time Frame: 2 hours post-dose]

Measure Type	Primary
Measure Title	Number of Participants Who Are Pain Free at 2 Hours Post-Dose
Measure Description	Pain severity was rated by the participants in a paper diary. Pain severity rating scale: 0 (no pain), 1 (mild), 2 (moderate), or 3 (severe). Pain free = rating of 0 (no pain) at 2 hours 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 (FAS): The FAS population includes all randomized participants who have at least one assessment within 2 hours post-dose (i.e., after baseline assessment).

Reporting Groups

	Description
Rizatriptan 10 mg ODT	Rizatriptan 10 mg Orally Disintegrating Tablet (ODT); one dose, treatment of a single migraine attack
Placebo	Matching placebo; one dose, treatment of a single migraine attack

Measured Values

	Rizatriptan 10 mg ODT	**Placebo**
Number of Participants Analyzed [units: participants]	**92**	**96**
Number of Participants Who Are Pain Free at 2 Hours Post-Dose [units: Participants]	**61**	**27**

No statistical analysis provided for Number of Participants Who Are Pain Free at 2 Hours Post-Dose

2. Secondary: Number of Participants With 24-Hour Sustained Pain Freedom [Time Frame: 24 hours post-dose]

Measure Type	Secondary
Measure Title	Number of Participants With 24-Hour Sustained Pain Freedom
Measure Description	24-hour sustained pain freedom (defined as pain freedom from 2 to 24 hours post-dose and no use of rescue medication). Participants assessed pain severity and use of rescue medication on a paper diary.
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.
The FAS population was used for this secondary variable of 24-hour sustained pain freedom, unless participants were otherwise identified as non-responders for this endpoint (i.e., took rescue up to 24 hours post-dose or were not pain free at 2 hours post-dose). To be included, participants must have also had a non-missing 24-hour assessment.

Reporting Groups

	Description
Rizatriptan 10 mg ODT	Rizatriptan 10 mg Orally Disintegrating Tablet (ODT); one dose, treatment of a single migraine attack
Placebo	Matching placebo; one dose, treatment of a single migraine attack

Measured Values

	Rizatriptan 10 mg ODT	**Placebo**
Number of Participants Analyzed [units: participants]	**92**	**96**
Number of Participants With 24-Hour Sustained Pain Freedom [units: Participants]	**48**	**17**

No statistical analysis provided for Number of Participants With 24-Hour Sustained Pain Freedom

3. Secondary: Number of Participants With no Rescue Use up to 24 Hours Post-Dose [Time Frame: 24 hours post-dose]

Measure Type	Secondary
Measure Title	Number of Participants With no Rescue Use up to 24 Hours Post-Dose
Measure Description	Participants recorded use of any rescue medication up to 24 hours after dosing with study medication on a paper diary.
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.

The FAS population included all randomized and treated participants.

Reporting Groups

	Description
Rizatriptan 10 mg ODT	Rizatriptan 10 mg Orally Disintegrating Tablet (ODT); one dose, treatment of a single migraine attack
Placebo	Matching placebo; one dose, treatment of a single migraine attack

Measured Values

	Rizatriptan 10 mg ODT	Placebo
Number of Participants Analyzed [units: participants]	**92**	**96**
Number of Participants With no Rescue Use up to 24 Hours Post-Dose [units: Participants]	**61**	**32**

No statistical analysis provided for Number of Participants With no Rescue Use up to 24 Hours Post-Dose

4. Secondary: Number of Participants With Absence of Photophobia at 2 Hours Post-dose [Time Frame: 2 hours post-dose]

Measure Type	Secondary
Measure Title	Number of Participants With Absence of Photophobia at 2 Hours Post-dose
Measure Description	Absence or presence of photophobia was recorded by the participants on a paper diary. Absence is defined as no photophobia at 2 hours 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.
The FAS population included all randomized participants who had at least one assessment within 2 hours post-dose (i.e., after baseline assessment).

Reporting Groups

	Description
Rizatriptan 10 mg ODT	Rizatriptan 10 mg Orally Disintegrating Tablet (ODT); one dose, treatment of a single migraine attack
Placebo	Matching placebo; one dose, treatment of a single migraine attack

Measured Values

	Rizatriptan 10 mg ODT	Placebo
Number of Participants Analyzed [units: participants]	**92**	**96**

Number of Participants With Absence of Photophobia at 2 Hours Post-dose [units: Participants]	**69**	**43**

No statistical analysis provided for Number of Participants With Absence of Photophobia at 2 Hours Post-dose

5. Secondary: Number of Participants With Absence of Phonophobia at 2 Hours Post-dose [Time Frame: 2 hours post-dose]

Measure Type	Secondary
Measure Title	Number of Participants With Absence of Phonophobia at 2 Hours Post-dose
Measure Description	Absence or presence of phonophobia was recorded by the participants on a paper diary. Absence is defined as no phonophobia at 2 hours 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.
The FAS population included all randomized participants who had at least one assessment within 2 hours post-dose (i.e., after baseline assessment).

Reporting Groups

	Description
Rizatriptan 10 mg ODT	Rizatriptan 10 mg Orally Disintegrating Tablet (ODT); one dose, treatment of a single migraine attack
Placebo	Matching placebo; one dose, treatment of a single migraine attack

Measured Values

	Rizatriptan 10 mg ODT	**Placebo**
Number of Participants Analyzed [units: participants]	**92**	**96**
Number of Participants With Absence of Phonophobia at 2 Hours Post-dose [units: Participants]	**72**	**55**

No statistical analysis provided for Number of Participants With Absence of Phonophobia at 2 Hours Post-dose

6. Secondary: Number of Participants With Absence of Nausea at 2 Hours Post-dose [Time Frame: 2 hours post-dose]

Measure Type	Secondary
Measure Title	Number of Participants With Absence of Nausea at 2 Hours Post-dose
Measure Description	Absence or presence of nausea was recorded by the participants on a paper diary. Absence is defined as no nausea at 2 hours 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.
The FAS population included all randomized participants who had at least one assessment within 2 hours post-dose (i.e., after baseline assessment).

Reporting Groups

	Description
Rizatriptan 10 mg ODT	Rizatriptan 10 mg Orally Disintegrating Tablet (ODT); one dose, treatment of a single migraine attack
Placebo	Matching placebo; one dose, treatment of a single migraine attack

Measured Values

	Rizatriptan 10 mg ODT	**Placebo**
Number of Participants Analyzed [units: participants]	**92**	**96**
Number of Participants With Absence of Nausea at 2 Hours Post-dose [units: Participants]	**82**	**73**

No statistical analysis provided for Number of Participants With Absence of Nausea at 2 Hours Post-dose

7. Secondary: Number of Participants With Absence of Functional Disability at 2 Hours Post-Dose [Time Frame: 2 hours post-dose]

Measure Type	Secondary
Measure Title	Number of Participants With Absence of Functional Disability at 2 Hours Post-Dose
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 bed rest. Absence of functional disability defined as a rating of normal at 2 hours 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.
The FAS population included all randomized participants who had at least one assessment within 2 hours post-dose (i.e., after baseline assessment).

Reporting Groups

	Description
Rizatriptan 10 mg ODT	Rizatriptan 10 mg Orally Disintegrating Tablet (ODT); one dose, treatment of a single migraine attack

Placebo	Matching placebo; one dose, treatment of a single migraine attack

Measured Values

	Rizatriptan 10 mg ODT	Placebo
Number of Participants Analyzed [units: participants]	**92**	**96**
Number of Participants With Absence of Functional Disability at 2 Hours Post-Dose [units: Participants]	**66**	**42**

No statistical analysis provided for Number of Participants With Absence of Functional Disability at 2 Hours Post-Dose

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Reporting Groups

	Description
Rizatriptan 10 mg ODT	Rizatriptan 10 mg Orally Disintegrating Tablet (ODT); one dose, treatment of a single migraine attack
Placebo	Matching placebo; one dose, treatment of a single migraine attack

Serious Adverse Events

	Rizatriptan 10 mg ODT	Placebo
Total, serious adverse events		
# participants affected / at risk	**0/92 (0.00%)**	**0/96 (0.00%)**

Other Adverse Events

Hide Other Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are	0%

reported	

Reporting Groups

	Description
Rizatriptan 10 mg ODT	Rizatriptan 10 mg Orally Disintegrating Tablet (ODT); one dose, treatment of a single migraine attack
Placebo	Matching placebo; one dose, treatment of a single migraine attack

Other Adverse Events

	Rizatriptan 10 mg ODT	Placebo
Total, other (not including serious) adverse events		
# participants affected / at risk	**6/92 (6.52%)**	**3/96 (3.13%)**
Gastrointestinal disorders		
Hyperchlorhydria * 1		
# participants affected / at risk	**2/92 (2.17%)**	**0/96 (0.00%)**
Nausea * 1		
# participants affected / at risk	**1/92 (1.09%)**	**0/96 (0.00%)**
General disorders		
Fatigue * 1		
# participants affected / at risk	**0/92 (0.00%)**	**1/96 (1.04%)**
Feeling cold * 1		
# participants affected / at risk	**0/92 (0.00%)**	**1/96 (1.04%)**
Feeling jittery * 1		
# participants affected / at risk	**1/92 (1.09%)**	**0/96 (0.00%)**
Pain * 1		
# participants affected / at risk	**1/92 (1.09%)**	**0/96 (0.00%)**
Musculoskeletal and connective tissue disorders		
Myalgia * 1		
# participants affected / at risk	**1/92 (1.09%)**	**0/96 (0.00%)**
Nervous system disorders		
Balance disorder * 1		
# participants affected / at risk	**1/92 (1.09%)**	**0/96 (0.00%)**
Dizziness * 1		
# participants affected / at risk	**2/92 (2.17%)**	**1/96 (1.04%)**
Respiratory, thoracic and mediastinal disorders		
Dyspnoea * 1		
# participants affected / at risk	**0/92 (0.00%)**	**1/96 (1.04%)**
Throat tightness * 1		
# participants affected / at risk	**1/92 (1.09%)**	**0/96 (0.00%)**

* Events were collected by non-systematic assessment

1 Term from vocabulary, MedDRA

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
In the Adverse Events section, all non-serious adverse experiences reported are post-treatment, up to the time of taking rescue medication or 14 days post-dose, whichever comes first.

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@merck.com

Publications:

Cady RK, Martin VT, Géraud G, Rodgers A, Zhang Y, Ho AP, Hustad CM, Ho TP, Connor KM, Ramsey KE. Rizatriptan 10-mg ODT for early treatment of migraine and impact of migraine education on treatment response. Headache. 2009 May;49(5):687-96.

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