



Clinical trial results:

An Open-Label Single-Dose Study to Evaluate the Pediatric Palatability of Maxalt Oral Disintegrating Tablets

Summary

| | |
|--------------------------|------------------|
| EudraCT number | 2011-002349-36 |
| Trial protocol | Outside EU/EEA |
| Global end of trial date | 28 February 2011 |

Results information

| | |
|--------------------------------|---------------|
| Result version number | v2 (current) |
| This version publication date | 16 March 2016 |
| First version publication date | 11 March 2015 |
| Version creation reason | |

Trial information

Trial identification

| | |
|-----------------------|----------|
| Sponsor protocol code | 0462-107 |
|-----------------------|----------|

Additional study identifiers

| | |
|------------------------------------|---|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | - |
| WHO universal trial number (UTN) | - |

Notes:

Sponsors

| | |
|------------------------------|--|
| Sponsor organisation name | Merck Sharp & Dohme Corp. |
| Sponsor organisation address | 2000 Galloping Hill Road, Kenilworth, NJ, United States, 07033 |
| Public contact | Clinical Trials Disclosure, Merck Sharp & Dohme Corp., ClinicalTrialsDisclosure@merck.com |
| Scientific contact | Clinical Trials Disclosure, Merck Sharp & Dohme Corp., ClinicalTrialsDisclosure@merck.com |

Notes:

Paediatric regulatory details

| | |
|--|---------------------|
| Is trial part of an agreed paediatric investigation plan (PIP) | Yes |
| EMA paediatric investigation plan number(s) | EMA-000084-PIP02-10 |
| Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial? | No |
| Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial? | Yes |

Notes:

Results analysis stage

| | |
|--|------------------|
| Analysis stage | Final |
| Date of interim/final analysis | 28 February 2011 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 28 February 2011 |
| Global end of trial reached? | Yes |
| Global end of trial date | 28 February 2011 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this study was to evaluate the palatability of rizatriptan benzoate orally disintegrating tablets (Maxalt-MLT™ ODT) in healthy young male and female subjects, 6 to less than 12 years of age, with a history of migraines, who were not experiencing a migraine on the day of the assessment.

Protection of trial subjects:

This study was conducted in conformance with Good Clinical Practice standards and applicable country and/or local statutes and regulations regarding ethical committee review, informed consent, and the protection of human subjects participating in biomedical research.

Background therapy: -

Evidence for comparator: -

| | |
|---|------------------|
| Actual start date of recruitment | 02 February 2011 |
| Long term follow-up planned | No |
| Independent data monitoring committee (IDMC) involvement? | No |

Notes:

Population of trial subjects

Subjects enrolled per country

| | |
|--------------------------------------|-------------------|
| Country: Number of subjects enrolled | United States: 12 |
| Worldwide total number of subjects | 12 |
| EEA total number of subjects | 0 |

Notes:

Subjects enrolled per age group

| | |
|---|----|
| In utero | 0 |
| Preterm newborn - gestational age < 37 wk | 0 |
| Newborns (0-27 days) | 0 |
| Infants and toddlers (28 days-23 months) | 0 |
| Children (2-11 years) | 12 |
| Adolescents (12-17 years) | 0 |
| Adults (18-64 years) | 0 |
| From 65 to 84 years | 0 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Screening occurred within 3 weeks prior to randomisation. Participants were 6 to less than 12 years of age with a history of migraines for at least 6 months but free of migraine on the day of study drug administration, weighed at least 20 kg, and were in good health at the time of screening.

Period 1

| | |
|------------------------------|--|
| Period 1 title | Single Dose Rizatriptan ODT (overall period) |
| Is this the baseline period? | Yes |
| Allocation method | Not applicable |
| Blinding used | Not blinded |

Arms

| | |
|------------------|--------------------------|
| Arm title | Rizatriptan benzoate ODT |
|------------------|--------------------------|

Arm description:

Subjects were administered a single dose of either 5-mg or 10-mg rizatriptan benzoate ODT in open label fashion with the specific dose determined by the subject's weight at predose on Day 1.

| | |
|--|--------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Rizatriptan Benzoate ODT |
| Investigational medicinal product code | |
| Other name | Maxalt-MLT™ ODT |
| Pharmaceutical forms | Oral lyophilisate |
| Routes of administration | Oral use |

Dosage and administration details:

Participants weighing 20-39.9 kg received a 5 mg dose of rizatriptan benzoate (Maxalt-MLT™ ODT) in an open-label fashion and those weighing 40 kg and above received a 10 mg dose of rizatriptan benzoate (Maxalt-MLT™ ODT) in an open-label fashion with the specific dose determined by the participant's weight at predose on Day 1. Participants were to fast from all food and drink except water for 1 hour prior to dose administration. To clear the palate and wet the oral mucosa, 120 mL of water was administered 5 minutes prior to dose administration. Subsequently, the investigator (or representative) provided each participant with the study drug tablet at weight-based dose with verbal instructions to close their mouth and not swallow the tablet allowing it to dissolve on their tongue. When they felt it had disappeared from their tongue, they were then permitted to swallow it.

| | |
|---------------------------------------|--------------------------|
| Number of subjects in period 1 | Rizatriptan benzoate ODT |
| Started | 12 |
| Completed | 12 |

Baseline characteristics

Reporting groups

| | |
|-----------------------|--------------------------|
| Reporting group title | Rizatriptan benzoate ODT |
|-----------------------|--------------------------|

Reporting group description:

Subjects were administered a single dose of either 5-mg or 10-mg rizatriptan benzoate ODT in open label fashion with the specific dose determined by the subject's weight at predose on Day 1.

| Reporting group values | Rizatriptan benzoate ODT | Total | |
|--|--------------------------|-------|--|
| Number of subjects | 12 | 12 | |
| Age categorical Units: Subjects | | | |
| In utero | 0 | 0 | |
| Preterm newborn infants (gestational age < 37 wks) | 0 | 0 | |
| Newborns (0-27 days) | 0 | 0 | |
| Infants and toddlers (28 days-23 months) | 0 | 0 | |
| Children (2-11 years) | 12 | 12 | |
| Adolescents (12-17 years) | 0 | 0 | |
| Adults (18-64 years) | 0 | 0 | |
| From 65-84 years | 0 | 0 | |
| 85 years and over | 0 | 0 | |
| Age continuous Units: years | | | |
| arithmetic mean | 8.8 | | |
| full range (min-max) | 6 to 11 | - | |
| Gender categorical Units: Subjects | | | |
| Female | 7 | 7 | |
| Male | 5 | 5 | |

End points

End points reporting groups

| | |
|--|--------------------------------|
| Reporting group title | Rizatriptan benzoate ODT |
| Reporting group description: Subjects were administered a single dose of either 5-mg or 10-mg rizatriptan benzoate ODT in open label fashion with the specific dose determined by the subject's weight at predose on Day 1. | |
| Subject analysis set title | Rizatriptan benzoate ODT 10 mg |
| Subject analysis set type | Per protocol |
| Subject analysis set description: Participants who received rizatriptan benzoate ODT 10 mg. | |
| Subject analysis set title | Rizatriptan benzoate ODT 5 mg |
| Subject analysis set type | Per protocol |
| Subject analysis set description: Participants who received rizatriptan benzoate ODT 5 mg. | |

Primary: Rizatriptan Palatability (Overall)

| | |
|---|---|
| End point title | Rizatriptan Palatability (Overall) ^[1] |
| End point description: A palatability taste test assessment was performed in the immediate moments (5 minutes) after challenge with the rizatriptan benzoate ODT. Five minutes after dose administration, the subjects were queried for taste with a specific, standardized question and the participant's response was recorded with a validated 5-point facial hedonic scale with matching descriptive labels (Very Bad=1; Bad=2; Average=3; Good=4; Very Good=5). | |
| End point type | Primary |
| End point timeframe: At 5 minutes after oral challenge with rizatriptan (Maxalt-MLT™ ODT) 5 mg and 10 mg. | |
| Notes: [1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point. Justification: Per protocol only summary statistics for palatability scores based on the 5 point hedonic scale were to be provided. | |

| End point values | Rizatriptan benzoate ODT | | | |
|------------------------------|--------------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 12 | | | |
| Units: Taste Score Responses | | | | |
| Very Bad (1) | 3 | | | |
| Bad (2) | 2 | | | |
| Average (3) | 2 | | | |
| Good (4) | 4 | | | |
| Very Good (5) | 1 | | | |

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse experiences (AEs) were collected from the time of screening until approximately 14 days after study drug administration.

| | |
|-----------------|------------|
| Assessment type | Systematic |
|-----------------|------------|

Dictionary used

| | |
|-----------------|--------|
| Dictionary name | MedDRA |
|-----------------|--------|

| | |
|--------------------|------|
| Dictionary version | 13.1 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|-------------------------------|
| Reporting group title | Rizatriptan benzoate ODT 5 mg |
|-----------------------|-------------------------------|

Reporting group description:

Subjects were administered a single dose of 5-mg rizatriptan benzoate ODT in open label fashion on Day 1.

| | |
|-----------------------|--------------------------------|
| Reporting group title | Rizatriptan benzoate ODT 10 mg |
|-----------------------|--------------------------------|

Reporting group description:

Subjects were administered a single dose of 10-mg rizatriptan benzoate ODT in open label fashion on Day 1.

| Serious adverse events | Rizatriptan benzoate ODT 5 mg | Rizatriptan benzoate ODT 10 mg | |
|---|-------------------------------|--------------------------------|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 3 (0.00%) | |
| number of deaths (all causes) | 0 | 0 | |
| number of deaths resulting from adverse events | 0 | 0 | |

Frequency threshold for reporting non-serious adverse events: 5 %

| Non-serious adverse events | Rizatriptan benzoate ODT 5 mg | Rizatriptan benzoate ODT 10 mg | |
|---|-------------------------------|--------------------------------|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 5 / 9 (55.56%) | 3 / 3 (100.00%) | |
| Investigations | | | |
| Blood pressure increased | | | |
| subjects affected / exposed | 1 / 9 (11.11%) | 0 / 3 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Eosinophil count increased | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 1 / 3 (33.33%) | |
| occurrences (all) | 0 | 1 | |
| Nervous system disorders | | | |

| | | | |
|--|----------------|----------------|--|
| Headache | | | |
| subjects affected / exposed | 3 / 9 (33.33%) | 2 / 3 (66.67%) | |
| occurrences (all) | 3 | 2 | |
| Migraine | | | |
| subjects affected / exposed | 1 / 9 (11.11%) | 0 / 3 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| General disorders and administration site conditions | | | |
| Facial pain | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 1 / 3 (33.33%) | |
| occurrences (all) | 0 | 1 | |
| Gastrointestinal disorders | | | |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 1 / 3 (33.33%) | |
| occurrences (all) | 0 | 1 | |
| Abdominal pain upper | | | |
| subjects affected / exposed | 1 / 9 (11.11%) | 0 / 3 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Oropharyngeal pain | | | |
| subjects affected / exposed | 1 / 9 (11.11%) | 0 / 3 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Musculoskeletal and connective tissue disorders | | | |
| Pain in jaw | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 1 / 3 (33.33%) | |
| occurrences (all) | 0 | 1 | |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported