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)	EMEA-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