Clinical trial results:
Active-Controlled Trial of the Safety and Tolerability of MP29-02 in Subjects with Chronic Allergic or Nonallergic Rhinitis

Summary

EudraCT number	2011-001368-23
Trial protocol	Outside EU/EEA
Global end of trial date	17 June 2009

Results information

Result version number	v1 (current)
This version publication date	29 July 2016
First version publication date	29 July 2016

Trial information

Trial identification

Sponsor protocol code	MP4000

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Meda Pharmaceuticals
Sponsor organisation address	265 Davidson Avenue, Suite 300, Somerset, United States, 08873-4120
Public contact	Group leader study managers, MEDA Pharma GmbH Co. KG, +49 617288801, 42b@medapharma.de
Scientific contact	Head Corporate Clinical Affairs, MEDA Pharma GmbH Co. KG, +49 617288801, 42b@medapharma.de

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMEA-000990-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	05 October 2010
Is this the analysis of the primary completion data?	Yes
Primary completion date	17 June 2009
Global end of trial reached?	Yes
Global end of trial date	17 June 2009
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the safety and tolerability of azelastine hydrochloride and fluticasone propionate combination nasal spray in chronic use daily over a 1-year period.

Protection of trial subjects:

No specific additional measures to minimise pain and distress were required. The patients could withdraw from Treatment at any time and for any reason.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	16 January 2008
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	India: 612
Worldwide total number of subjects	612
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)	1
Adolescents (12-17 years)	36
Adults (18-64 years)	569
From 65 to 84 years	6
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Subjects 12 to 80 years of age with a history of chronic rhinitis symptoms due to perennial allergic rhinitis, perennial nonallergic rhinitis, or VMR who might benefit from continuous therapy with MP29-02 were considered for entry into the study. Subjects who met the study entry criteria were enrolled following an initial 7-day screening period.

Period 1

Period 1 title	overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	MP29-02 nasal spray

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Azelastine hydrochloride and fluticasone propionate
Investigational medicinal product code	MP29-02
Other name	
Pharmaceutical forms	Nasal spray
Routes of administration	Intranasal use , Topical use

Dosage and administration details:

Mode of Administration: Topical/intranasal spray
Dose: 137 mcg azelastine hydrochloride and 50 mcg fluticasone propionate/ spray
Regimen: 1 spray per nostril bid (morning [AM] and evening [PM])
Duration of Treatment: 12 months

Arm title	Fluticasone nasal spray

Arm description: -

Arm type	Active comparator
Investigational medicinal product name	Fluticasone propionate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray
Routes of administration	Intranasal use , Topical use

Dosage and administration details:

Mode of Administration: Topical/intranasal spray
Dose: 50 mcg fluticasone propionate/ spray
Regimen: 2 sprays per nostril qd (AM)
Duration of Treatment: 12 months

Number of subjects in period 1	MP29-02 nasal spray	Fluticasone nasal spray
Started	405	207
Completed	312	152
Not completed	93	55
Consent withdrawn by subject	12	8
Abnormal test procedure results	2	-
Treatment failure	-	2
Adverse event, non-fatal	11	6
Other	2	3
Administrative problems	15	6
Non-compliance	5	3
Did not have an end of study CRF page	5	4
Lost to follow-up	38	20
Protocol deviation	3	3

Baseline characteristics

Reporting groups	
Reporting group title	MP29-02 nasal spray
Reporting group description: -	
Reporting group title	Fluticasone nasal spray
Reporting group description: -	

Reporting group values	MP29-02 nasal spray	Fluticasone nasal spray	Total
Number of subjects	405	207	612
Age categorical Units: Subjects			
Adolescents (12-17 years)	28	8	36
Adults (18-64 years)	373	196	569
65 years and over	3	3	6
Not recorded	1	0	1
Gender categorical Units: Subjects			
Female	164	97	261
Male	240	110	350
Not recorded	1	0	1

End points

End points reporting groups

Reporting group title	MP29-02 nasal spray
Reporting group description: -	
Reporting group title	Fluticasone nasal spray
Reporting group description: -	
Subject analysis set title	Safety population for MP29-02
Subject analysis set type	Safety analysis
Subject analysis set description: Safety population for MP29-02.	
Subject analysis set title	Safety population for Fluticasone Propionate
Subject analysis set type	Safety analysis
Subject analysis set description: Safety population for Fluticasone Propionate.	

Primary: Number of AEs Reported

End point title	Number of AEs Reported[1]
End point description:	
End point type	Primary
End point timeframe: Safety and tolerability assessments were made at Months 1, 3, 6, 9, and 12. Phone contact was made at Months 2, 4, 5, 7, 8, 10, and 11 during the 12-month evaluation period.	

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: No statistical analysis for the safety end point - number of AEs reported - was performed.

End point values	Safety population for MP29-02	Safety population for Fluticasone Propionate		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	404	207		
Units: number of subjects				
All Treatment-Emergent AEs	653	313		
All Treatment-Related AEs	61	46		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Safety and tolerability assessments were made at Months 1, 3, 6, 9, and 12. Phone contact was made at Months 2, 4, 5, 7, 8, 10, and 11 during the 12-month evaluation period.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	11.1

Reporting groups

Reporting group title	Fluticasone nasal spray
Reporting group description: -	
Reporting group title	MP29-02 nasal spray

Reporting group description: -

Serious adverse events	Fluticasone nasal spray	MP29-02 nasal spray	
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 207 (0.48%)	3 / 404 (0.74%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 207 (0.00%)	1 / 404 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Dengue fever			
subjects affected / exposed	0 / 207 (0.00%)	1 / 404 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis			
subjects affected / exposed	1 / 207 (0.48%)	0 / 404 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicitis			

subjects affected / exposed	0 / 207 (0.00%)	1 / 404 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	1 / 207 (0.48%)	0 / 404 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 2.7 %

Non-serious adverse events	Fluticasone nasal spray	MP29-02 nasal spray	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	92 / 207 (44.44%)	188 / 404 (46.53%)	
Nervous system disorders			
Headache			
subjects affected / exposed	28 / 207 (13.53%)	50 / 404 (12.38%)	
occurrences (all)	28	50	
Dysgeusia			
subjects affected / exposed	1 / 207 (0.48%)	11 / 404 (2.72%)	
occurrences (all)	1	11	
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	22 / 207 (10.63%)	33 / 404 (8.17%)	
occurrences (all)	22	33	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	5 / 207 (2.42%)	20 / 404 (4.95%)	
occurrences (all)	5	20	
Nasal congestion			
subjects affected / exposed	8 / 207 (3.86%)	12 / 404 (2.97%)	
occurrences (all)	8	12	
Infections and infestations			
Rhinitis			

subjects affected / exposed occurrences (all)	5 / 207 (2.42%) 5	11 / 404 (2.72%) 11	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
29 November 2007	Protocol amended to include change in methodology of the study (increase of patients in one treatment arm of the sub-study)
21 January 2008	Protocol amended to include administrative modifications related to the implementation of the first protocol amendment

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported