Clinical trial results:
Placebo-Controlled Study of Mometasone Furoate Nasal Spray (MFNS) 200 mcg QD in the Relief of Nasal Congestion Associated With Seasonal Allergic Rhinitis (SAR)

Summary

EudraCT number	2014-004920-23
Trial protocol	Outside EU/EEA
Global end of trial date	09 October 2008

Results information

Result version number	v1
This version publication date	13 June 2016
First version publication date	19 July 2015

Trial information

Trial identification

Sponsor protocol code	P05583

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00728416
WHO universal trial number (UTN)	-
Other trial identifiers	Merck Protocol Number: MK-0887-160

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)	No
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	09 October 2008
Is this the analysis of the primary completion data?	Yes
Primary completion date	09 October 2008
Global end of trial reached?	Yes
Global end of trial date	09 October 2008
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 assess the efficacy in relieving the symptom of nasal congestion with MFNS 200 mcg given once daily compared to placebo in subjects with symptomatic SAR.

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	28 July 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	United States: 333
Worldwide total number of subjects	333
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)	0
Adolescents (12-17 years)	28
Adults (18-64 years)	294
From 65 to 84 years	11

85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants 12 years of age or older with symptomatic SAR were recruited. Additional inclusion and exclusion criteria applied.

Pre-assignment

Screening details:

Participants were screened for study inclusion over Day -14 to Day -3.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Mometasone furoate nasal spray

Arm description:

Mometasone furoate nasal spray 200 mcg QD (once per day)

Arm type	Experimental
Investigational medicinal product name	mometasone furoate
Investigational medicinal product code	
Other name	MK-0887, Nasonex Nasal Spray
Pharmaceutical forms	Nasal spray
Routes of administration	Intranasal use

Dosage and administration details:

MFNS 50 mcg/spray: two sprays in each nostril once daily (ie, 200 mcg QD) for 15 days

Arm title	Placebo Nasal Spray

Arm description:

Matching placebo nasal spray

Arm type	Placebo
Investigational medicinal product name	placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray
Routes of administration	Intranasal use

Dosage and administration details:

Matching placebo nasal spray: 2 sprays in each nostril once daily for 15 days

Number of subjects in period 1	Mometasone furoate nasal spray	Placebo Nasal Spray
Started	168	165
Completed	166	163
Not completed	2	2
Consent withdrawn by subject	1	-
Adverse event, non-fatal	1	1
Treatment Failure	-	1

Baseline characteristics

Reporting groups	
Reporting group title	Mometasone furoate nasal spray
Reporting group description:	
Mometasone furoate nasal spray 200 mcg QD (once per day)	
Reporting group title	Placebo Nasal Spray
Reporting group description:	
Matching placebo nasal spray	

Reporting group values	Mometasone furoate nasal spray	Placebo Nasal Spray	Total
Number of subjects	168	165	333
Age categorical Units: Subjects			
Children (2-11 years)	14	14	28
Adolescents (12-17 years)	148	146	294
Adults (18-64 years)	6	5	11
Gender categorical Units: Subjects			
Female	109	103	212
Male	59	62	121

End points

End points reporting groups

Reporting group title	Mometasone furoate nasal spray
Reporting group description:	
Mometasone furoate nasal spray 200 mcg QD (once per day)	
Reporting group title	Placebo Nasal Spray
Reporting group description:	
Matching placebo nasal spray	

Primary: The change from Baseline in average AM/PM PRIOR nasal congestion score over 15 days

End point title	The change from Baseline in average AM/PM PRIOR nasal congestion score over 15 days
End point description:	
Nasal congestion was scored on a scale of 0 = none, 1 = mild, 2 = moderate, 3 = severe. PRIOR (the subject's status over the previous 12 hours [reflective]). Baseline is the average score from the 3 days prior to the first dose of study drug.	
End point type	Primary
End point timeframe:	
15 days of treatment	

End point values	Mometasone furoate nasal spray	Placebo Nasal Spray		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	168[1]	165[2]		
Units: Units on a scale				
least squares mean (standard deviation)	-0.71 (± 0.55)	-0.4 (± 0.55)		

Notes:

[1] - The standard deviation is pooled.

[2] - The standard deviation is pooled.

Statistical analyses

Statistical analysis title	Comparison of Treatment Groups
Statistical analysis description:	
The change from Baseline in average AM/PM PRIOR nasal congestion score over 15 days: MFNS 200 mcg daily vs placebo. The difference in LS means (MFNS - Placebo) was calculated from an ANCOVA model with treatment, site and baseline AM/PM PRIOR Nasal Congestion Score as covariates.	
Comparison groups	Mometasone furoate nasal spray v Placebo Nasal Spray
Number of subjects included in analysis	333
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Difference in LS Means
Point estimate	-0.31

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.43
upper limit	-0.19

Secondary: The change from Baseline in average AM/PM PRIOR total nasal symptom score (TNSS) over 15 days

End point title	The change from Baseline in average AM/PM PRIOR total nasal symptom score (TNSS) over 15 days

End point description:

Total nasal symptom score is a composite of 4 symptoms, each is scored on a scale of 0 = none, 1 = mild, 2 = moderate, 3 = severe. The total can range from 0 to 12. PRIOR (the subject's status over the previous 12 hours [reflective]). Baseline is the average score from the 3 days prior to the first dose of study drug.

End point type	Secondary

End point timeframe:

15 days of treatment

End point values	Mometasone furoate nasal spray	Placebo Nasal Spray		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	168[3]	165[4]		
Units: Units on a scale				
least squares mean (standard deviation)	-3 (± 2.03)	-1.73 (± 2.03)		

Notes:

[3] - The standard deviation is pooled.

[4] - The standard deviation is pooled.

Statistical analyses

Statistical analysis title	Comparison of Treatment Groups

Statistical analysis description:

The change from Baseline in average AM/PM PRIOR TNSS over 15 days: MFNS 200 mcg daily vs placebo. The difference in LS means (MFNS - Placebo) was calculated from an ANCOVA model with treatment, site and baseline AM/PM TNSS as covariates.

Comparison groups	Mometasone furoate nasal spray v Placebo Nasal Spray
Number of subjects included in analysis	333
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Difference in LS Means
Point estimate	-1.27

Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.72
upper limit	-0.83

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

Day 1 up to 30 days after study completion/discontinuation (up to 45 days)

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	11.1

Reporting groups

Reporting group title	Mometasone furoate nasal spray

Reporting group description:

Mometasone furoate nasal spray 200 mcg QD (once per day)

Reporting group title	Placebo Nasal Spray

Reporting group description:

Matching placebo nasal spray

Serious adverse events	Mometasone furoate nasal spray	Placebo Nasal Spray	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 168 (0.00%)	0 / 165 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			

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

Non-serious adverse events	Mometasone furoate nasal spray	Placebo Nasal Spray	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 168 (0.00%)	0 / 165 (0.00%)	

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.

Justification: No non-serious adverse events (incidence ≥ 5%) were reported during the study.

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