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	2014-004918-28
Trial protocol	Outside EU/EEA
Global end of trial date	14 October 2008

Results information

Result version number	v1 (current)
This version publication date	10 February 2016
First version publication date	13 June 2015

Trial information

Trial identification

Sponsor protocol code	P05528

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00733005
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)	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	14 October 2008
Is this the analysis of the primary completion data?	Yes
Primary completion date	14 October 2008
Global end of trial reached?	Yes
Global end of trial date	14 October 2008
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

This study seeks to prospectively demonstrate that Nasonex is better than placebo in relieving nasal congestion in patients with seasonal allergic rhinitis (SAR). The primary hypothesis is that Mometasone Furoate Nasal Spray (MFNS) is more effective than placebo in reducing the AM/PM PRIOR nasal congestion.

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: 324
Worldwide total number of subjects	324
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)	15
Adults (18-64 years)	302
From 65 to 84 years	7
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Participants screened for this study were 12 years of age or older, had at least a 2-year history of seasonal allergic rhinitis (SAR) which exacerbates during the study season, and were clinically symptomatic at the Screening and Baseline visits.

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	Investigator, Carer, Subject, 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 nasal spray (MFNS)
Investigational medicinal product code	
Other name	Nasonex, MK-0887, SCH 032088
Pharmaceutical forms	Inhalation solution
Routes of administration	Inhalation 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	Inhalation solution
Routes of administration	Inhalation 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	162	162
Completed	160	159
Not completed	2	3
Consent withdrawn by subject	-	1
Adverse event, non-fatal	-	1
Treatment Failure	-	1
Protocol deviation	2	-

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	162	162	324
Age categorical Units: Subjects			
Adolescents (12-17 years)	7	8	15
Adults (between 18 and 64 years)	148	154	302
From 65 to 84 years	7	0	7
Gender categorical Units: Subjects			
Female	113	116	229
Male	49	46	95

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, and 3 = severe. PRIOR (the participant's status over the previous 12 hours [reflective]). A change from baseline score that is negative indicates an improvement in condition.	
End point type	Primary
End point timeframe:	
Baseline and Day 15	

End point values	Mometasone furoate nasal spray	Placebo nasal spray		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	162[1]	162[2]		
Units: Units on a scale				
least squares mean (standard deviation)	-0.68 (± 0.59)	-0.57 (± 0.59)		

Notes:

[1] - All randomized participants who took ≥1 study drug dose and were evaluable for this end point.

[2] - All randomized participants who took ≥1 study drug dose and were evaluable for this end point.

Statistical analyses

Statistical analysis title	AM/PM PRIOR Nasal Congestion
Statistical analysis description:	
LS means, Pstd (pooled std), and 95% Confidence Intervals are obtained from an ANCOVA model with treatment (trt) and site effect with baseline score as a covariate.	
Comparison groups	Mometasone furoate nasal spray v Placebo nasal spray
Number of subjects included in analysis	324
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.102
Method	ANCOVA

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

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

End point description:

Total nasal symptom score (TNSS) 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 and a higher score indicating more severe nasal symptoms. A change from baseline score that is negative indicates an improvement in condition.

End point type	Secondary

End point timeframe:

Baseline and Day 15

End point values	Mometasone furoate nasal spray	Placebo nasal spray		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	162[3]	162[4]		
Units: Units on a scale				
least squares mean (standard deviation)	-2.61 (± 2.1)	-2.06 (± 2.1)		

Notes:

[3] - All randomized participants who took ≥1 study drug dose and were evaluable for this end point.

[4] - All randomized participants who took ≥1 study drug dose and were evaluable for this end point.

Statistical analyses

Statistical analysis title	AM/PM PRIOR Total Nasal Symptom Score

Statistical analysis description:

LS means, Pstd (pooled std), and 95% Confidence Intervals are obtained from an ANCOVA model with treatment (trt) and site effect with baseline score as a covariate.

Comparison groups	Mometasone furoate nasal spray v Placebo nasal spray
Number of subjects included in analysis	324
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.019
Method	ANCOVA
Confidence interval	
level	95 %

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

Up to Day 18

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 / 162 (0.00%)	0 / 162 (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	Mometasone furoate nasal spray	Placebo nasal spray	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (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 exceeded the 5% threshold for any reporting group.

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