Clinical trial results:
A Double-blind Placebo-controlled, Randomized, Parallel-group, Multicenter Clinical Trial to Evaluate Efficacy and Safety of Mometasone Furoate Nasal Spray in Children With Adenoid Hypertrophy. SNORE Study

Summary

EudraCT number	2014-004917-10
Trial protocol	Outside EU/EEA
Global end of trial date	25 January 2010

Results information

Result version number	v2 (current)
This version publication date	10 March 2016
First version publication date	29 July 2015
Version creation reason	

Trial information

Trial identification

Sponsor protocol code	P05155

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00552032
WHO universal trial number (UTN)	-
Other trial identifiers	Merck Protocol Number: MK-0887-138

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	25 January 2010
Is this the analysis of the primary completion data?	Yes
Primary completion date	25 January 2010
Global end of trial reached?	Yes
Global end of trial date	25 January 2010
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The purpose of this study is to determine whether 8 weeks treatment with mometasone furoate nasal spray (MFNS), twice daily, is safe and effective in treating adenoid hypertrophy in children.

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	31 August 2007
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	Mexico: 125
Country: Number of subjects enrolled	Venezuela, Bolivarian Republic of: 7
Worldwide total number of subjects	132
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)	132
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:

This study enrolled children aged 2 to 11 years with adenoid hypertrophy (AH) with or without otitis media effusion (OME).

Pre-assignment

Screening details:

135 participants were screened, of those, 132 were randomized in the intent-to-treat (ITT) population (MFNS n=66, placebo=66) and 96 in the per protocol (PP) population (MFNS n=49, placebo n=47).

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

Arms

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

Arm description:

1 spray (50 mcg) in each nostril twice daily (equivalent to 200 mcg per day) administered for 8 weeks. There was a blinded follow-up period of 16 weeks, resulting in study duration of 24 weeks (6 months).

Arm type	Experimental
Investigational medicinal product name	mometasone furoate
Investigational medicinal product code	
Other name	Nasonex, SCH 032088, MK-0887
Pharmaceutical forms	Inhalation solution
Routes of administration	Inhalation use

Dosage and administration details:

1 spray (50 mcg) in each nostril twice daily (equivalent to 200 mcg per day) administered for 8 weeks. There was a blinded follow-up period of 16 weeks, resulting in study duration of 24 weeks (6 months).

Arm title	Placebo nasal spray

Arm description:

1 spray in each nostril twice daily administered for 8 weeks. There was a blinded follow-up period of 16 weeks, resulting in study duration of 24 weeks (6 months).

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:

1 spray in each nostril twice daily administered for 8 weeks. There was a blinded follow-up period of 16 weeks, resulting in study duration of 24 weeks (6 months).

Number of subjects in period 1	Mometasone Furoate nasal spray	Placebo nasal spray
Started	66	66
Completed	49	47
Not completed	17	19
Consent withdrawn by subject	2	2
Lost to follow-up	8	5
Protocol deviation	7	12

Baseline characteristics

Reporting groups	
Reporting group title	Mometasone Furoate nasal spray
Reporting group description:	
1 spray (50 mcg) in each nostril twice daily (equivalent to 200 mcg per day) administered for 8 weeks. There was a blinded follow-up period of 16 weeks, resulting in study duration of 24 weeks (6 months).	
Reporting group title	Placebo nasal spray
Reporting group description:	
1 spray in each nostril twice daily administered for 8 weeks. There was a blinded follow-up period of 16 weeks, resulting in study duration of 24 weeks (6 months).	

Reporting group values	Mometasone Furoate nasal spray	Placebo nasal spray	Total
Number of subjects	66	66	132
Age categorical			
Units: Subjects			
Age Continuous			
Units: years			
arithmetic mean	5.56	5.36	
standard deviation	± 2.27	± 2.5	-
Gender, Male/Female			
Units: participants			
Female	32	23	55
Male	34	43	77
Adenoid/Choana (A/C) Index Grade			
Units: Score on a Scale			
arithmetic mean	3.3	3.4	
standard deviation	± 0.44	± 0.49	-

End points

End points reporting groups

Reporting group title	Mometasone Furoate nasal spray

Reporting group description:

1 spray (50 mcg) in each nostril twice daily (equivalent to 200 mcg per day) administered for 8 weeks. There was a blinded follow-up period of 16 weeks, resulting in study duration of 24 weeks (6 months).

Reporting group title	Placebo nasal spray

Reporting group description:

1 spray in each nostril twice daily administered for 8 weeks. There was a blinded follow-up period of 16 weeks, resulting in study duration of 24 weeks (6 months).

Primary: Change From Baseline in Adenoid/Choana (A/C) Index Grade

End point title	Change From Baseline in Adenoid/Choana (A/C) Index Grade

End point description:

Changes in adenoid size were assessed by nasopharyngoscopic examination and were determined using the Adenoid/Choana (A/C) Index. Grades were assigned to intervals of A/C ratio percentages: grade I (0-25%), II (26-50%), III (51-75%) and IV (76-100%). Changes in adenoid size were expressed as the mean difference between grades at baseline and study visit. Positive values indicated a decrease in adenoid size, a 0 value indicated that size remained the same, and negative values indicated an increase in adenoid size.

End point type	Primary

End point timeframe:

Baseline (visit 2), Week 4 (visit 3), Week 8 (visit 4)

End point values	Mometasone Furoate nasal spray	Placebo nasal spray		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	65[1]	63[2]		
Units: Score on a Scale				
arithmetic mean (standard deviation)				
Change at Visit 3 (n=65 MFNS, n=63 Placebo)	0.3 (± 0.6)	0.2 (± 0.5)		
Change at Visit 4 (n=61 MFNS, n=58 Placebo)	0.4 (± 0.7)	0.3 (± 0.7)		

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	Change from Baseline to Visit 5
Comparison groups	Mometasone Furoate nasal spray v Placebo nasal spray

Number of subjects included in analysis	128
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.05
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	0.22
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.21
upper limit	0.23

Secondary: Total Severity Symptom Scores: Morning and Evening (AM & PM)

End point title	Total Severity Symptom Scores: Morning and Evening (AM & PM)

End point description:

Symptoms were assessed by whole-number linear scale to grade their severity. Scores were recorded AM & PM (a difference of 12 hours) & were based on severity within 12 hours of prior recording. The following symptoms were evaluated: Snoring; Nasal obstruction & discharge; Breathing difficulty; Oral respiration; Ear pain. Severity was graded according to the following scale: 0=absent; 1=mild; 2=moderate; 3=severe. Severity was scored individually and summed to obtain the Total Symptom Severity Score. The maximum total score possible was 36 daily; 18 for both AM (6 symptoms times max severity of 3) and PM.

End point type	Secondary

End point timeframe:

Baseline (Visit 2), Week 4 (Visit 3), Week 8 (Visit 4)

End point values	Mometasone Furoate nasal spray	Placebo nasal spray		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	66[3]	66[4]		
Units: Score on a scale				
arithmetic mean (standard deviation)				
Visit 2 AM (n=66 MFNS, n=66 Placebo)	9.4 (± 2.5)	9.9 (± 3.3)		
Visit 3 AM (n=64 MFNS, n=65 Placebo)	5.4 (± 3.8)	6.4 (± 3.7)		
Visit 4 AM (n=62 MFNS, n=60 Placebo)	4.2 (± 3.6)	5.5 (± 3.5)		
Visit 2 PM (n=66 MFNS, n=66 Placebo)	9.9 (± 3.2)	10.2 (± 2.8)		
Visit 3 PM (n=64 MFNS, n=65 Placebo)	6.3 (± 3.7)	7 (± 3.6)		
Visit 4 PM (n=62 MFNS, n=60 Placebo)	4.8 (± 3.8)	5.7 (± 3.8)		

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

No statistical analyses for this end point

Secondary: Total Frequency Symptom Scores: AM & PM

End point title	Total Frequency Symptom Scores: AM & PM

End point description:

Symptoms were assessed by whole-number linear scale to grade their frequency. Scores were recorded AM & PM (a difference of 12 hours) & were based on frequency within 12 hours of prior recording. The following signs/symptoms were evaluated: Snoring; Nasal obstruction & discharge; Breathing difficulty; Oral respiration; Ear pain. Frequency was graded according to the following scale: 0=absent; 1=intermittent; 2=persistent. The frequency of symptoms was scored individually and summed to obtain the Total Frequency Symptom Score. The maximum total score possible was 24 daily; 12 for both AM (6 symptoms times max frequency of 2) and PM.

End point type	Secondary

End point timeframe:

Baseline (Visit 2), Week 4 (Visit 3), Week 8 (Visit 4)

End point values	Mometasone Furoate nasal spray	Placebo nasal spray		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	66[5]	66[6]		
Units: Score on a scale				
arithmetic mean (standard deviation)				
Visit 2 AM (n=66 MFNS, n=66 Placebo)	7.3 (± 1.9)	7.3 (± 2.4)		
Visit 3 AM (n=64 MFNS, n=65 Placebo)	4.4 (± 2.7)	5.4 (± 2.6)		
Visit 4 AM (n=62 MFNS, n=60 Placebo)	3.7 (± 2.8)	4.4 (± 2.5)		
Visit 2 PM (n=66 MFNS, n=66 Placebo)	7.6 (± 2.2)	8 (± 2.1)		
Visit 3 PM (n=64 MFNS, n=65 Placebo)	5.3 (± 2.8)	5.7 (± 2.6)		
Visit 4 PM (n=62 MFNS, n=60 Placebo)	4.1 (± 2.9)	4.6 (± 2.7)		

Notes:

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

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

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Bilateral Tympanogram Results of: Normal, Abnormal, or Not Done

End point title	Number of Participants with Bilateral Tympanogram Results of: Normal, Abnormal, or Not Done

End point description:

Tympanometry was performed in children ages 2-11 by certified audiologists. Results were categorized based on audiologist's assessment as either being normal (normal pressure in the middle ear with normal mobility of the eardrum and the conduction bones), abnormal (abnormal pressure in the middle ear and/or abnormal mobility of the eardrum and the conduction bones), or tympanometry was not done (evaluation not completed). Results were assessed at baseline, Week 4 (Visit 3), and endpoint Week 8 (end of treatment).

End point type	Secondary

End point timeframe:

Baseline (Visit 2), Week 4 (Visit 3), Week 8 (Visit 4)

End point values	Mometasone Furoate nasal spray	Placebo nasal spray		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	66[7]	66[8]		
Units: Participants				
number (not applicable)				
Visit 2- Normal (n=66 MFNS, n=66 Placebo)	35	39		
Visit 2- Abnormal (n=66 MFNS, n=66 Placebo)	25	22		
Visit 2- Not Done (n=66 MFNS, n=66 Placebo)	6	5		
Visit 3- Normal (n=65 MFNS, n=65 Placebo)	44	33		
Visit 3- Abnormal (n=65 MFNS, n=65 Placebo)	14	22		
Visit 3- Not Done (n=65 MFNS, n=65 Placebo)	7	10		
Visit 4- Normal (n=62 MFNS, n=60 Placebo)	45	39		
Visit 4- Abnormal (n=62 MFNS, n=60 Placebo)	16	19		
Visit 4- Not Done (n=62 MFNS, n=60 Placebo)	1	2		

Notes:

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

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

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Otoscopic Results of: Normal or Abnormal

End point title	Number of Participants With Otoscopic Results of: Normal or Abnormal

End point description:

Otoscopic examination was performed of the right and left ear canals at baseline (visit 2) and each visit throughout treatment (visit 3 and visit 4). Results were categorized based on audiologist's assessment as either being normal (ear canal structures appear normal) or abnormal (ear canal structures appear abnormal).

End point type	Secondary

End point timeframe:

Baseline (Visit 2), Week 4 (Visit 3), Week 8 (Visit 4)

End point values	Mometasone Furoate nasal spray	Placebo nasal spray		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	66[9]	66[10]		
Units: Participants				
number (not applicable)				
Right Otoscopy: Visit 2- Normal (n=66, n=66)	50	51		

Right Otoscopy: Visit 2- Abnormal (n=66, n=66)	16	15		
Right Otoscopy Visit 3- Normal (n=65, n=65)	54	53		
Right Otoscopy Visit 3- Abnormal (n=65, n=65)	11	12		
Right Otoscopy Visit 4- Normal (n=62, n=60)	49	52		
Right Otoscopy Visit 4- Abnormal (n=62, n=60)	13	8		
Left Otoscopy: Visit 2- Normal (n=66, n=66)	49	52		
Left Otoscopy: Visit 2- Abnormal (n=66, n=66)	17	14		
Left Otoscopy Visit 3- Normal (n=65, n=65)	51	55		
Left Otoscopy Visit 3- Abnormal (n=65, n=65)	14	10		
Left Otoscopy Visit 4- Normal (n=62, n=60)	48	52		
Left Otoscopy Visit 4- Abnormal (n=62, n=60)	14	8		

Notes:

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

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

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Rhinoscopic-Inferior Turbinates Results of: Normal, Hypertrophic, and Hypotrophic

End point title	Number of Participants with Rhinoscopic-Inferior Turbinates Results of: Normal, Hypertrophic, and Hypotrophic

End point description:

Rhinoscopic examination of the inferior turbinates was performed at baseline (visit 2) and each visit throughout treatment (visit 3 and visit 4). Results were categorized based on investigator's assessment as either being normal appearance (normal size) , hypertrophic (swollen/normal size increased), or hypotrophic (normal size diminished).

End point type	Secondary

End point timeframe:

Baseline (Visit 2), Week 4 (Visit 3), Week 8 (Visit 4)

End point values	Mometasone Furoate nasal spray	Placebo nasal spray		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	66[11]	66[12]		
Units: Participants				
number (not applicable)				
Visit 2- Normal Appearance (n=66, n=66)	50	46		
Visit 2 Hypertrophic (n=66, n=66)	16	20		
Vist 2 Hypotrophic (n=66, n=66)	0	0		

Visit 3 Normal Appearance (n=65, n=65)	46	48		
Visit 3 Hypertrophic (n=65, n=65)	19	17		
Visit 3 Hypotrophic (n=65, n=65)	0	0		
Visit 4 Normal Appearance (n=62, n=60)	45	42		
Visit 4 Hypertrophic (n=62, n=60)	17	18		
Visit 4 Hypotrophic (n=62, n=60)	0	0		

Notes:

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

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

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Rhinoscopic- Middle Meatus Results of: Patent, Partial Obstruction or Total Obstruction

End point title	Number of Participants With Rhinoscopic- Middle Meatus Results of: Patent, Partial Obstruction or Total Obstruction

End point description:

Rhinoscopic examination of the middle meatus was performed at baseline (visit 2) and each visit throughout treatment (visit 3 and visit 4). Results were categorized based on investigator's assessment into 3 categories: patent (easily observed), partial obstruction (partially blocked from view), or total obstruction (completely blocked from view).

End point type	Secondary

End point timeframe:

Baseline (Visit 2), Week 4 (Visit 3), Week 8 (Visit 4)

End point values	Mometasone Furoate nasal spray	Placebo nasal spray		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	66[13]	66[14]		
Units: Participants				
number (not applicable)				
Visit 2- Patent (n=66, n=66)	62	60		
Visit 2- Partial Obstruction (n=66, n=66)	3	5		
Visit 2- Total Obstruction (n=66, n=66)	1	1		
Visit 3- Patent (n=65, n=65)	61	61		
Visit 3- Partial Obstruction (n=65, n=65)	4	2		
Visit 3- Total Obstruction (n=65, n=65)	0	2		
Visit 4- Patent (n=62, n=60)	56	53		
Visit 4- Partial Obstruction (n= 62, n=60)	6	4		
Visit 4- Total Obstruction (n=62, n=60)	0	3		

Notes:

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

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

Statistical analyses

No statistical analyses for this end point

Secondary: Rhinomanometry Results- Left and Right Nasal Fossa: Inspiratory Resistance

End point title	Rhinomanometry Results- Left and Right Nasal Fossa: Inspiratory Resistance

End point description:

Rhinomanometry examination of the left & right Nasal Fossa was performed at baseline (visit 2) and each visit throughout treatment (visit 3 and visit 4) in participants ages 7-11 years. Rhinomanometry is a test of nasal function that measures air pressure and the rate of airflow in the nasal airway during respiration by means of equipment. These findings were used to calculate inspiratory nasal airway resistance reported in Pascal/centimeter^3/second (Pa/cm^3/sec).

End point type	Secondary

End point timeframe:

Baseline (Visit 2), Week 4 (Visit 3), Week 8 (Visit 4)

End point values	Mometasone Furoate nasal spray	Placebo nasal spray		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	19[15]	20[16]		
Units: Pa/cm^3/sec				
arithmetic mean (standard deviation)				
Visit 2- Left Nasal Fossa (n=19, n=20)	2.111 (± 4.372)	3.28 (± 7.852)		
Visit 3- Left Nasal Fossa (n=18, n=18)	6.341 (± 22.759)	1.934 (± 2.234)		
Visit 4- Left Nasal Fossa (n=19, n=19)	31.074 (± 131.718)	54.724 (± 229.437)		
Visit 2- Right Nasal Fossa (n=19, n=20)	2.985 (± 8.527)	6.535 (± 24.836)		
Visit 3- Right Nasal Fossa (n=18, n=18)	1.823 (± 4.454)	3.026 (± 8.258)		
Visit 4- Right Nasal Fossa (n=19, n=19)	2.56 (± 6.918)	43.621 (± 174.535)		

Notes:

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

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

Statistical analyses

No statistical analyses for this end point

Secondary: Rhinomanometry Results- Left and Right Nasal Fossa: Expiratory Resistance

End point title	Rhinomanometry Results- Left and Right Nasal Fossa: Expiratory Resistance

End point description:

Rhinomanometry examination of the left & right Nasal Fossa was performed at baseline (visit 2) and each visit throughout treatment (visit 3 and visit 4) in participants ages 7-11 years. Rhinomanometry is a test of nasal function that measures air pressure and the rate of airflow in the nasal airway during respiration by means of equipment. These findings were used to calculate expiratory nasal airway resistance reported in Pascal/centimeter^3/second (Pa/cm^3/sec).

End point type	Secondary

End point timeframe:

Baseline (Visit 2), Week 4 (Visit 3), Week 8 (Visit 4)

End point values	Mometasone Furoate nasal spray	Placebo nasal spray		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	19[17]	20[18]		
Units: Pa/cm^3/sec				
arithmetic mean (standard deviation)				
Visit 2- Left Nasal Fossa (n=19, n=20)	1.771 (± 2.764)	3.994 (± 9.416)		
Visit 3- Left Nasal Fossa (n=18, n=18)	2.937 (± 8.196)	1.478 (± 1.647)		
Visit 4- Left Nasal Fossa (n=19, n=19)	13.488 (± 32.344)	4.148 (± 13.999)		
Visit 2- Right Nasal Fossa (n=19, n=20)	2.625 (± 6.868)	1.083 (± 1.109)		
Visit 3- Right Nasal Fossa (n=18, n=18)	2.189 (± 4.678)	3.646 (± 8.313)		
Visit 4- Right Nasal Fossa (n=19, n=19)	0.961 (± 0.758)	2.792 (± 6.318)		

Notes:

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

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

Statistical analyses

No statistical analyses for this end point

Secondary: Rhinomanometry Results- Left and Right Nasal Fossa: Inspiration Flow at 75 Pa

End point title	Rhinomanometry Results- Left and Right Nasal Fossa: Inspiration Flow at 75 Pa

End point description:

Rhinomanometry examination of the left & right Nasal Fossa was performed at baseline (visit 2) and each visit throughout treatment (visit 3 and visit 4) in participants ages 7-11 years. Rhinomanometry is a test of nasal function that measures air pressure and the rate of airflow in the nasal airway during respiration by means of equipment. Inspiration flow was calculated at 75 Pa.

End point type	Secondary

End point timeframe:

Baseline (Visit 2), Week 4 (Visit 3), Week 8 (Visit 4)

End point values	Mometasone Furoate nasal spray	Placebo nasal spray		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	19[19]	20[20]		
Units: cm^3/sec				
arithmetic mean (standard deviation)				
Visit 2- Left Nasal Fossa (n=19, n=20)	200.53 (± 140.492)	178.933 (± 129.272)		
Visit 3- Left Nasal Fossa (n=18, n=18)	222.152 (± 141.74)	151.268 (± 130.115)		
Visit 4- Left Nasal Fossa (n=19, n=19)	194.208 (± 100.746)	172.346 (± 102.607)		
Visit 2- Right Nasal Fossa (n=19, n=20)	183.562 (± 121.78)	161.958 (± 138.673)		
Visit 3- Right Nasal Fossa (n=18, n=18)	228.661 (± 149.318)	197.266 (± 123.763)		
Visit 4- Right Nasal Fossa (n=19, n=19)	215.4 (± 157.794)	183.368 (± 117.677)		

Notes:

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

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

Statistical analyses

No statistical analyses for this end point

Secondary: Rhinomanometry Results- Left and Right Nasal Fossa: Expiratory Flow at 75 Pa

End point title	Rhinomanometry Results- Left and Right Nasal Fossa: Expiratory Flow at 75 Pa

End point description:

Rhinomanometry examination of the left & right Nasal Fossa was performed at baseline (visit 2) and each visit throughout treatment (visit 3 and visit 4) in participants ages 7-11 years. Rhinomanometry is a test of nasal function that measures air pressure and the rate of airflow in the nasal airway during respiration by means of equipment. Expiratory flow was calculated at 75 Pa.

End point type	Secondary

End point timeframe:

Baseline (Visit 2), Week 4 (Visit 3), Week 8 (Visit 4)

End point values	Mometasone Furoate nasal spray	Placebo nasal spray		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	19[21]	20[22]		
Units: cm^3/sec				
arithmetic mean (standard deviation)				
Visit 2- Left Nasal Fossa (n=19, n=20)	190.024 (± 146.067)	166.93 (± 116.802)		
Visit 3- Left Nasal Fossa (n=18, n=18)	225.911 (± 154.83)	173.139 (± 151.783)		
Visit 4- Left Nasal Fossa (n=19, n=19)	181.026 (± 119.728)	192.374 (± 134.337)		
Visit 2- Right Nasal Fossa (n=19, n=20)	160.531 (± 117.988)	166.302 (± 132.754)		

Visit 3- Right Nasal Fossa (n=18, n=18)	209.676 (± 157.215)	209.787 (± 151.298)		
Visit 4- Right Nasal Fossa (n=19, n=19)	195.108 (± 163.411)	176.587 (± 111.421)		

Notes:

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

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

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Pure-Tone Audiometric Results of: Normal, Abnormal, or Not Done

End point title	Number of Participants with Pure-Tone Audiometric Results of: Normal, Abnormal, or Not Done

End point description:

Pure-tone audiometry was performed in children ages 7-11 by certified audiologists. Results were categorized based on audiologist's assessment as either being normal (within normal limits), abnormal (outside normal limits), or audiometry was not done (not performed). Results were assessed at baseline, Week 4 (Visit 3), and endpoint Week 8 (end of treatment).

End point type	Secondary

End point timeframe:

Baseline (Visit 2), Week 4 (Visit 3), Week 8 (Visit 4)

End point values	Mometasone Furoate nasal spray	Placebo nasal spray		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	19[23]	21[24]		
Units: Participants				
number (not applicable)				
Visit 2- Normal (n=19 MFNS, n=21 Placebo)	13	18		
Visit 2- Abnormal (n=19 MFNS, n=21 Placebo)	5	2		
Visit 2- Not Done (n=19 MFNS, n= 21 Placebo)	1	1		
Visit 3- Normal (n=20 MFNS, n=21 Placebo)	15	20		
Visit 3- Abnormal (n=20 MFNS, n=21 Placebo)	4	1		
Visit 3- Not Done (n=20 MFNS, n=21 Placebo)	1	0		
Visit 4- Normal (n=19 MFNS, n=20 Placebo)	15	18		
Visit 4- Abnormal (n=19 MFNS, n=20 Placebo)	2	2		
Visit 4- Not Done (n=19 MFNS, n=20 Placebo)	2	0		

Notes:

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

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

Statistical analyses

No statistical analyses for this end point

Secondary: Acoustic Rhinometry Results- Minimal Cross-Sectional Area: Left and Right Nasal Fossa

End point title	Acoustic Rhinometry Results- Minimal Cross-Sectional Area: Left and Right Nasal Fossa

End point description:

Acoustic rhinometry examination of the left & right Nasal Fossa was performed by principal investigators at baseline & each visit throughout treatment in participants ages 7-11 years. Acoustic rhinometry is a technique intended for assessment of the geometry of the nasal cavity and nasopharynx and for evaluating nasal obstruction. The technique is based on an analysis of sound waves reflected from the nasal cavities. Measurements were taken for each side of the nose (nasopharyngeal minimum cross-sectional area) & were reported in cm^3.

End point type	Secondary

End point timeframe:

Baseline (Visit 2), Week 4 (Visit 3), Week 8 (Visit 4)

End point values	Mometasone Furoate nasal spray	Placebo nasal spray		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	19[25]	20[26]		
Units: cm^3				
arithmetic mean (standard deviation)				
Visit 2- Left Nasal Fossa (n=19, n=20)	0.599 (± 0.567)	0.491 (± 0.265)		
Visit 3- Left Nasal Fossa (n=18, n=18)	0.608 (± 0.485)	0.594 (± 0.403)		
Visit 4- Left Nasal Fossa (n=19, n=19)	0.662 (± 0.444)	0.661 (± 0.444)		
Visit 2- Right Nasal Fossa (n=19, n=20)	0.532 (± 0.467)	0.577 (± 0.381)		
Visit 3- Right Nasal Fossa (n=18, n=18)	0.581 (± 0.405)	0.596 (± 0.383)		
Visit 4- Right Nasal Fossa (n=19, n=19)	0.734 (± 0.599)	0.814 (± 0.675)		

Notes:

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

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

Statistical analyses

No statistical analyses for this end point

Secondary: Acoustic Rhinometry Results- Nasopharyngeal Volume (NPV): Left and Right Nasal Fossa

End point title	Acoustic Rhinometry Results- Nasopharyngeal Volume (NPV): Left and Right Nasal Fossa

End point description:

Acoustic rhinometry examination of the left & right Nasal Fossa was performed by principal investigators at baseline & each visit throughout treatment in participants ages 7-11 years. Acoustic rhinometry is a technique intended for assessment of the geometry of the nasal cavity and nasopharynx and for evaluating nasal obstruction. The technique is based on an analysis of sound waves reflected from the

nasal cavities.

End point type	Secondary

End point timeframe:

Baseline (Visit 2), Week 4 (Visit 3), Week 8 (Visit 4)

End point values	Mometasone Furoate nasal spray	Placebo nasal spray		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	19[27]	20[28]		
Units: cm^3				
arithmetic mean (standard deviation)				
Visit 2- Left Nasal Fossa (n=19, n=20)	4.245 (± 1.954)	4.117 (± 3.554)		
Visit 3- Left Nasal Fossa (n=18, n=18)	3.725 (± 1.944)	3.489 (± 1.589)		
Visit 4- Left Nasal Fossa (n=19, n=19)	3.631 (± 0.905)	3.084 (± 1.724)		
Visit 2- Right Nasal Fossa (n=19, n=20)	3.566 (± 1.629)	4.489 (± 2.941)		
Visit 3- Right Nasal Fossa (n=18, n=18)	4.183 (± 1.341)	4.884 (± 3.591)		
Visit 4- Right Nasal Fossa (n=19, n=19)	3.774 (± 1.24)	3.275 (± 1.083)		

Notes:

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

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

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Pediatric Sleep Questionnaire (PSQ)-Impact on Health-Related Quality of Life (HRQL) Results of: Mild, Moderate, or Severe

End point title	Number of Participants with Pediatric Sleep Questionnaire (PSQ)- Impact on Health-Related Quality of Life (HRQL) Results of: Mild, Moderate, or Severe

End point description:

PSQ consists of 90 variables divided into 3 different factors: snoring, somnolence, and behavior. All positive Snoring and Somnolence answers scored with Yes=1 and No=0, and scores averaged to obtain a total score between 0.00 and 1.00. Behavior factor scored between 1 (never)-3 (always), and scores averaged for total score of 1 to 3. Increased scores indicate increasing abnormality of sleep. Based on determined cut-offs, participants were categorized as having mild, moderate, or severe discomfort due to interference of sleep.

End point type	Secondary

End point timeframe:

Baseline (Visit 2), Week 4 (Visit 3), Week 8 (Visit 4)

End point values	Mometasone Furoate nasal spray	Placebo nasal spray		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	66[29]	65[30]		
Units: Participants				
number (not applicable)				
Visit 2- Mild (n=66 MFNS, n=65 Placebo)	33	30		
Visit 2- Moderate (n=66 MFNS, n=65 Placebo)	17	26		
Visit 2- Severe (n=66 MFNS, n=65 Placebo)	16	9		
Visit 3- Mild (n=65 MFNS, n=65 Placebo)	50	45		
Visit 3- Moderate (n=65 MFNS, n=Placebo)	11	17		
Visit 3- Severe (n=65 MFNS, n=65 Placebo)	4	3		
Visit 4- Mild (n=62 MFNS, n=59 Placebo)	49	47		
Visit 4- Moderate (n=62 MFNS, n=59 Placebo)	13	10		
Visit 4- Severe (n=62 MFNS, n= 59 Placebo)	0	2		

Notes:

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

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

Statistical analyses

No statistical analyses for this end point

Secondary: Quality of Life Questionnaire (PedsQL) Total Score (Ages 2-4)

End point title	Quality of Life Questionnaire (PedsQL) Total Score (Ages 2-4)

End point description:

The impact on quality of life (QOL) was measured by a general pediatric health questionnaire. Versions were self-administered & answered by participants' parents. This modular instrument consists of 21 items using a 5-point scale: from 0 (never) to 4 (almost always). Items are reversed scored and linearly transformed to a 0-100 scale as follows: 0=100, 1=75, 2=50, 3=25, 4=0. 4 dimensions (physical, emotional, social, & school functioning) are scored. Total score is sum of all the items over the number of items answered on all the scales. Higher scores indicate a better health related QOL. At baseline (visit 2), 52 randomized participants were between 2 and 4 years old, 23 participants in MFNS & 29 participants in Placebo group. Questionnaire was answered in accordance with the actual age of each participant at each visit.

End point type	Secondary

End point timeframe:

Baseline (Visit 2), Week 4 (Visit 3), Week 8 (Visit 4)

End point values	Mometasone Furoate nasal spray	Placebo nasal spray		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	23[31]	29[32]		
Units: Score on a scale				
arithmetic mean (standard deviation)				
Visit 2 (n= 23 MFNS, n=29 Placebo)	78.442 (± 13.114)	78.017 (± 14.769)		
Visit 3 (n=22 MFNS, n= 28 Placebo)	80.438 (± 15.827)	78.486 (± 15.707)		
Visit 4 (n=18 MFNS, n=25 Placebo)	80.137 (± 15.161)	82.701 (± 11.911)		

Notes:

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

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

Statistical analyses

No statistical analyses for this end point

Secondary: Quality of Life Questionnaire (PedsQL) Total Score (Ages 5-7)

End point title	Quality of Life Questionnaire (PedsQL) Total Score (Ages 5-7)

End point description:

The impact on quality of life (QOL) was measured by a general pediatric health questionnaire. Versions were self-administered & answered by participants' parents. Questionnaire consists of 23 items using a 3-point scale: from 0 (not at all), 2 (sometimes), 4 (a lot). Items are reversed scored and linearly transformed to a 0-100 scale as follows: 0=100, 1=75, 2=50, 3=25, 4=0. 4 dimensions (physical, emotional, social, & school functioning) are scored. Total score is sum of all the items over the number of items answered on all the scales. Higher scores indicate a better health related QOL. At baseline (visit 2), 52 randomized participants were between 5 and 7 years old, 28 participants in MFNS & 24 subjects in Placebo group. Questionnaire was answered in accordance with the actual age of each participant at each visit.

End point type	Secondary

End point timeframe:

Baseline (Visit 2), Week 4 (Visit 3), Week 8 (Visit 4)

End point values	Mometasone Furoate nasal spray	Placebo nasal spray		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	28[33]	24[34]		
Units: Score on a scale				
arithmetic mean (standard deviation)				
Visit 2 (n= 28 MFNS, n=24 Placebo)	78.14 (± 15.74)	79.03 (± 11.35)		
Visit 3 (n=28 MFNS, n= 23 Placebo)	81.56 (± 13.64)	84.07 (± 12.26)		
Visit 4 (n=28 MFNS, n=22 Placebo)	83.54 (± 13.63)	82.71 (± 13.52)		

Notes:

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

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

Statistical analyses

No statistical analyses for this end point

Secondary: Quality of Life Questionnaire (PedsQL) Total Score (Ages 8-12)

End point title	Quality of Life Questionnaire (PedsQL) Total Score (Ages 8-12)

End point description:

The impact on quality of life (QOL) was measured by a general pediatric health questionnaire. Versions were self-administered & answered by participants' parents. This modular instrument consists of 23 items using a 5-point scale: from 0 (never) to 4 (almost always). Items are reversed scored and linearly transformed to a 0-100 scale as follows: 0=100, 1=75, 2=50, 3=25, 4=0. 4 dimensions (physical, emotional, social, & school functioning) are scored. Total score is sum of all the items over the number of items answered on all the scales. Higher scores indicate a better health related QOL. At baseline (visit 2), 28 randomized participants were between 8-12 years old, 15 participants in MFNS & 13 participants in Placebo group. Questionnaire was answered in accordance with the actual age of each participant at each visit.

End point type	Secondary

End point timeframe:

Baseline (Visit 2), Week 4 (Visit 3), Week 8 (Visit 4)

End point values	Mometasone Furoate nasal spray	Placebo nasal spray		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	15[35]	14[36]		
Units: Score on a scale				
arithmetic mean (standard deviation)				
Visit 2 (n= 15 MFNS, n=13 Placebo)	76.014 (± 10.266)	76.839 (± 10.828)		
Visit 3 (n=15 MFNS, n= 14 Placebo)	82.971 (± 15.054)	84.006 (± 14.033)		
Visit 4 (n=15 MFNS, n=13 Placebo)	85.725 (± 12.033)	83.946 (± 10.023)		

Notes:

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

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

Statistical analyses

No statistical analyses for this end point

Secondary: Obstructive Sleep Apnea-18 (OSA-18) Questionnaire Total Score

End point title	Obstructive Sleep Apnea-18 (OSA-18) Questionnaire Total Score

End point description:

18 items of the survey were graded on a 7-point ordinal scale. Caregivers were asked to describe how often in the last 4 weeks had the child exhibited specific symptoms according to the following scale: 1: none of the time; 2: hardly any of the time; 3: a little of the time; 4: some of the time; 5: a good bit of the time; 6: most of the time; 7: all of the time. All scores were summed (total score: 18-126). Grading was as follows: -Scores < 60 suggest a slight impact on health related quality of life (HRQL) -Scores 60-80 suggest a moderate impact -Scores over 80 suggest a great impact 1 participant in Placebo group did not answer this questionnaire at baseline.

End point type	Secondary

End point timeframe:

Baseline (Visit 2), Week 4 (Visit 3), Week 8 (Visit 4)

End point values	Mometasone Furoate nasal spray	Placebo nasal spray		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	66[37]	65[38]		
Units: Score on a scale				
arithmetic mean (standard deviation)				
Visit 2 (n=66 MFNS, n=65 Placebo)	62.742 (± 19.951)	60.169 (± 19.123)		
Visit 3 (n=65 MFNS, n= 65 Placebo)	47.138 (± 18.806)	48.769 (± 18.748)		
Visit 4 (n=62 MFNS, n= 59 Placebo)	42.742 (± 17.88)	43.068 (± 18.87)		

Notes:

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

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

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Rhinoscopic- Septum Results of: Aligned, Non-Obstructive, or Obstructive Deviation

End point title	Number of Participants With Rhinoscopic- Septum Results of: Aligned, Non-Obstructive, or Obstructive Deviation

End point description:

Rhinoscopic examination of the septum was performed at baseline (visit 2) and each visit throughout treatment (visit 3 and visit 4). Results were categorized based on investigator's assessment as either being aligned (septum is aligned), non-obstructive (septum is not aligned but the deviation is non-obstructive), or obstructive (septum is deviated and obstructive) deviation.

End point type	Secondary

End point timeframe:

Baseline (Visit 2), Week 4 (Visit 3), Week 8 (Visit 4)

End point values	Mometasone Furoate nasal spray	Placebo nasal spray		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	66[39]	66[40]		
Units: Participants				
number (not applicable)				
Visit 2 Aligned (n= 66, n=66)	65	63		
Visit 2 Non-obstructive Deviation (n= 66, n=66)	1	3		
Vist 2 Obstructive Deviation (n=66, n=66)	0	0		
Visit 3 Aligned (n=65, n=65)	64	62		
Visit 3 Non-obstructive Deviation (n=65, n=65)	1	3		

Visit 3 Obstructive Deviation (n=65, n=65)	0	0		
Visit 4 Aligned (n=62, n=60)	61	57		
Visit 4 Non-obstructive Deviation (n=62, n=60)	1	3		
Visit 4 -Obstructive Deviation (n=62, n=60)	0	0		

Notes:

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

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

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to Week 24

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	13.0

Reporting groups

Reporting group title	Placebo nasal spray

Reporting group description:

1 spray in each nostril twice daily administered for 8 weeks. There was a blinded follow-up period of 16 weeks, resulting in study duration of 24 weeks (6 months).

Reporting group title	Mometasone Furoate nasal spray

Reporting group description:

1 spray (50 mcg) in each nostril twice daily (equivalent to 200 mcg per day) administered for 8 weeks. There was a blinded follow-up period of 16 weeks, resulting in study duration of 24 weeks (6 months).

Serious adverse events	Placebo nasal spray	Mometasone Furoate nasal spray	
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 66 (4.55%)	2 / 66 (3.03%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Respiratory, thoracic and mediastinal disorders			
Oropharyngeal Pain			
subjects affected / exposed	1 / 66 (1.52%)	0 / 66 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural Effusion			
subjects affected / exposed	1 / 66 (1.52%)	0 / 66 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Orchitis			
subjects affected / exposed	1 / 66 (1.52%)	0 / 66 (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 / 66 (0.00%)	1 / 66 (1.52%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pharyngitis			
subjects affected / exposed	1 / 66 (1.52%)	0 / 66 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	1 / 66 (1.52%)	0 / 66 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper Respiratory Tract Infection			
subjects affected / exposed	0 / 66 (0.00%)	1 / 66 (1.52%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Placebo nasal spray	Mometasone Furoate nasal spray	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	17 / 66 (25.76%)	18 / 66 (27.27%)	
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	4 / 66 (6.06%)	5 / 66 (7.58%)	
occurrences (all)	5	10	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	4 / 66 (6.06%)	1 / 66 (1.52%)	
occurrences (all)	4	1	
Epistaxis			
subjects affected / exposed	4 / 66 (6.06%)	3 / 66 (4.55%)	
occurrences (all)	14	4	
Infections and infestations			

Pharyngitis			
subjects affected / exposed	3 / 66 (4.55%)	4 / 66 (6.06%)	
occurrences (all)	4	7	
Nasopharyngitis			
subjects affected / exposed	4 / 66 (6.06%)	3 / 66 (4.55%)	
occurrences (all)	4	3	
Pharyngotonsillitis			
subjects affected / exposed	4 / 66 (6.06%)	2 / 66 (3.03%)	
occurrences (all)	6	2	
Sinusitis			
subjects affected / exposed	2 / 66 (3.03%)	4 / 66 (6.06%)	
occurrences (all)	2	5	

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

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

The results of this study as presented are drawn from the clinical study report and should be reviewed with caution as there were inaccuracies in the database resulting from medication errors in some participants.

Notes: