Clinical trial results:
Open Label Pilot Trial, Evaluating the Role of Nasonex in the Management of Nasal Obstruction Secondary to Adenoids Hypertrophy in Children

Summary

EudraCT number	2014-004923-40
Trial protocol	Outside EU/EEA
Global end of trial date	30 September 2009

Results information

Result version number	v1 (current)
This version publication date	05 April 2016
First version publication date	19 July 2015

Trial information

Trial identification

Sponsor protocol code	P04367 - Lebanon

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01098071
WHO universal trial number (UTN)	-
Other trial identifiers	Merck Registration Number: MK-0887-096

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	30 September 2009
Is this the analysis of the primary completion data?	Yes
Primary completion date	30 September 2009
Global end of trial reached?	Yes
Global end of trial date	30 September 2009
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To document the short term & long term effect of treatment with Nasonex (mometasone furoate nasal spray) in moderate to severe adenoids hypertrophy (which cause > 50% obstruction of the posterior choanae).

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	01 May 2006
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	Lebanon: 34
Worldwide total number of subjects	34
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)	2
Children (2-11 years)	32
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:

34 participants enrolled in the study, 19 completed treatment and follow-up, and 15 patients discontinued the study.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Mometasone furoate nasal spray

Arm description:

One spray (50 mcg per spray) in each nostril once daily (100 mcg daily) for 3 months

Arm type	Experimental
Investigational medicinal product name	Mometasone Furoate nasal spray
Investigational medicinal product code	
Other name	Nasonex®, MK-0887, SCH 032088
Pharmaceutical forms	Nasal spray
Routes of administration	Intranasal use

Dosage and administration details:

One spray (50 mcg per spray) in each nostril once daily (100 mcg daily) for 3 months. After initial priming, each actuation of the pump delivers a metered spray containing 100 mcg of suspension (50 mcg mometasone furoate monohydrate).

Number of subjects in period 1	Mometasone furoate nasal spray
Started	34
Completed	19
Not completed	15
Lost to follow-up	13
Surgery (adenoidectomy)	2

Baseline characteristics

Reporting groups	
Reporting group title	Mometasone furoate nasal spray
Reporting group description:	
One spray (50 mcg per spray) in each nostril once daily (100 mcg daily) for 3 months	

Reporting group values	Mometasone furoate nasal spray	Total	
Number of subjects	34	34	
Age categorical Units: Subjects			
Age Continuous Units: Years			
arithmetic mean	4.84		
full range (min-max)	0.5 to 9.25	-	
Gender, Male/Female Units: participants			
Female	15	15	
Male	19	19	
Region of Enrollment Units: Subjects			
Lebanon	34	34	

End points

End points reporting groups

Reporting group title	Mometasone furoate nasal spray

Reporting group description:

One spray (50 mcg per spray) in each nostril once daily (100 mcg daily) for 3 months

Primary: Severity of nasal obstruction symptoms at Baseline and Week 12 as measured by the total clinical score

End point title	Severity of nasal obstruction symptoms at Baseline and Week 12 as measured by the total clinical score[1]

End point description:

Clinical score (based on a 5 point grading system) was assessed for each of 5 nasal obstruction symptoms (oral/mouth breathing, snoring, restless sleep, frequent waking-ups during the night, and obstructive breathing during sleep). Each nasal obstruction symptom was estimated by the parent/guardian of the participant and scored on a scale of 0 (best) to 1 (worst). Total clinical score is a score on a scale (0 = no symptoms [best score] and 5 = worst symptoms [worst score]). Only participants who completed the study were included in this endpoint.

End point type	Primary

End point timeframe:

Baseline and Week 12 (Visit 2)

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 between-group statistical analyses were performed for this endpoint.

End point values	Mometasone furoate nasal spray			
Subject group type	Reporting group			
Number of subjects analysed	19			
Units: Score on a scale				
arithmetic mean (full range (min-max))				
Baseline score	3.89 (2 to 5)			
Score at Week 12	1.26 (0 to 4)			

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants referred to surgery (adenoidectomy) within 12 weeks of start of therapy

End point title	Number of participants referred to surgery (adenoidectomy) within 12 weeks of start of therapy[2]

End point description:

End point type	Primary

End point timeframe:

Baseline to 12 weeks (Visit 2)

Notes:

[2] - 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 between-group statistical analyses were performed for this endpoint.

End point values	Mometasone furoate nasal spray			
Subject group type	Reporting group			
Number of subjects analysed	19			
Units: Participants				
number (not applicable)	2			

Statistical analyses

No statistical analyses for this end point

Primary: Degree of posterior choana obstruction at Baseline and Week 12

End point title	Degree of posterior choana obstruction at Baseline and Week 12[3]

End point description:

The degree of obstruction of the posterior choana was assessed by endoscopy. Endoscopy grading consisted of Grade I (minimum), Grade II, and Grade III (maximum). Grade I was defined as <50% obstruction, Grade II was defined as 50-75% obstruction, and Grade III was defined as >75% obstruction.

End point type	Primary

End point timeframe:

Baseline and Week 12 (Visit 2)

Notes:

[3] - 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 between-group statistical analyses were performed for this endpoint.

End point values	Mometasone furoate nasal spray			
Subject group type	Reporting group			
Number of subjects analysed	19			
Units: Percent obstruction				
arithmetic mean (full range (min-max))				
Baseline score	85 (70 to 95)			
Score at Week 12	61 (40 to 80)			

Statistical analyses

No statistical analyses for this end point

Secondary: Severity of rhinorrhea at Baseline and Week 12

End point title	Severity of rhinorrhea at Baseline and Week 12

End point description:

Rhinorrhea is a symptom of allergic rhinitis. Rhinorrhea was assessed using a 3-point scale (0 = no symptoms [best score] and 3 = symptom interferes with daily life activity [worst score]) in participants with suspected allergic rhinitis at baseline.

End point type	Secondary

End point timeframe:

Baseline and Week 12 (Visit 2)

End point values	Mometasone furoate nasal spray			
Subject group type	Reporting group			
Number of subjects analysed	10			
Units: Score on a scale				
arithmetic mean (full range (min-max))				
Baseline score	0.95 (0 to 3)			
Score at Week 12	0.37 (0 to 2)			

Statistical analyses

No statistical analyses for this end point

Secondary: Severity of nasal congestion at Baseline and Week 12

End point title	Severity of nasal congestion at Baseline and Week 12

End point description:

Nasal congestion is a symptom of allergic rhinitis. Nasal congestion was assessed using a 3-point scale (0 = no symptoms [best score] and 3 = symptom interferes with daily life activity [worst score]) in participants with suspected allergic rhinitis at baseline.

End point type	Secondary

End point timeframe:

Baseline and Week 12

End point values	Mometasone furoate nasal spray			
Subject group type	Reporting group			
Number of subjects analysed	10			
Units: Score on a scale				
arithmetic mean (full range (min-max))				
Baseline score	0.79 (0 to 3)			
Score at Week 12	0.32 (0 to 3)			

Statistical analyses

No statistical analyses for this end point

Secondary: Severity of nasal itching at Baseline and Week 12

End point title	Severity of nasal itching at Baseline and Week 12

End point description:

Nasal itching is a symptom of allergic rhinitis. Nasal itching was assessed using a 3-point scale (0 = no symptoms [best score] and 3 = symptom interferes with daily life activity [worst score]) in participants with suspected allergic rhinitis at baseline.

End point type	Secondary

End point timeframe:

Baseline and Week 12

End point values	Mometasone furoate nasal spray			
Subject group type	Reporting group			
Number of subjects analysed	10			
Units: Score on a scale				
arithmetic mean (full range (min-max))				
Baseline score	0.74 (0 to 3)			
Score at Week 12	0.37 (0 to 1)			

Statistical analyses

No statistical analyses for this end point

Secondary: Severity of sneezing at Baseline and Week 12

End point title	Severity of sneezing at Baseline and Week 12

End point description:

Sneezing is a symptom of allergic rhinitis. Sneezing was assessed using a 3-point scale (0 = no symptoms [best score] and 3 = symptom interferes with daily life activity [worst score]) in participants with suspected allergic rhinitis at baseline.

End point type	Secondary

End point timeframe:

Baseline and Week 12

End point values	Mometasone furoate nasal spray			
Subject group type	Reporting group			
Number of subjects analysed	10			
Units: Score on a scale				
arithmetic mean (full range (min-max))				
Baseline score	0.89 (0 to 3)			
Score at Week 12	0.37 (0 to 2)			

Statistical analyses

No statistical analyses for this end point

Secondary: Severity of eye symptoms at Baseline and Week 12

End point title	Severity of eye symptoms at Baseline and Week 12

End point description:

Eye symptoms are a symptom of allergic rhinitis. Eye symptoms were assessed using a 3-point scale (0 = no symptoms [best score] and 3 = symptom interferes with daily life activity [worst score]) in participants with suspected allergic rhinitis at baseline.

End point type	Secondary

End point timeframe:

Baseline and Week 12

End point values	Mometasone furoate nasal spray			
Subject group type	Reporting group			
Number of subjects analysed	10			
Units: Score on a scale				
arithmetic mean (full range (min-max))				
Baseline score	0.68 (0 to 3)			
Score at Week 12	0.16 (0 to 1)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

From Screening visit up to 30 days after completion or discontinuation from study (up to 15 months)

Adverse event reporting additional description:

In this study, symptoms of allergic rhinitis (rhinorrhea, nasal congestion, nasal itching, sneezing, and eye symptoms) were not reported as adverse events.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	13.0

Reporting groups

Reporting group title	Mometasone furoate nasal spray

Reporting group description:

One spray (50 mcg per spray) in each nostril once daily (100 mcg daily) for 3 months

Serious adverse events	Mometasone furoate nasal spray		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 34 (0.00%)		
number of deaths (all causes)	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		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 34 (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 AEs were reported during the course of 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