Clinical trial results:
A study of long-term (12-24 weeks) administration of mometasone furoate nasal spray in pediatric subjects with perennial allergic rhinitis (Protocol No. P06333)

Summary

EudraCT number	2014-004922-16
Trial protocol	Outside EU/EEA
Global end of trial date	28 December 2010

Results information

Result version number	v1 (current)
This version publication date	16 February 2016
First version publication date	15 July 2015

Trial information

Trial identification

Sponsor protocol code	P06333

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01165424
WHO universal trial number (UTN)	-
Other trial identifiers	Protocol number: MK-0887-175

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	28 December 2010
Is this the analysis of the primary completion data?	Yes
Primary completion date	28 December 2010
Global end of trial reached?	Yes
Global end of trial date	28 December 2010
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Mometasone furoate nasal spray (MFNS) is a once-a-day product. This is a multi-center, open-label study of MFNS in children with perennial allergic rhinitis. MFNS will be administered to pediatric participants (3-15 years old) with perennial allergic rhinitis at a dose of 100 to 200 µg/day (once daily) for 12 weeks. Participants (participant's legal representatives) provided consent to continue treatment beyond 12 weeks will receive treatment for up to 24 weeks. At each clinic visit, observation of adverse events, nasal symptom scores, and nasal findings will be evaluated. The presence/absence of serious adverse events and trial procedure-related AEs will be reviewed 30 days after the end of the follow-up.

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	08 April 2010
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	Japan: 80
Worldwide total number of subjects	80
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)	56
Adolescents (12-17 years)	24
Adults (18-64 years)	0

From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

This study was performed at 7 clinical sites in Japan.

Pre-assignment

Screening details:

Ninety-eight participants were tentatively enrolled after giving consent. Of these, 80 who satisfied the eligibility criteria after the pretreatment observation period of at
least 7 days were registered.

Period 1

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

Arms

Arm title	Mometasone furoate nasal spray

Arm description:

Mometasone furoate (MFNS) 50 µg spray device. For participants aged 3 to 11 years: one spray per nostril once daily (100 µg/day) in the morning for up to 24 weeks and for participant aged 12 to 15 years: 2 sprays per nostril once daily (200 µg/day) in the morning for up to 24 weeks.

Arm type	Experimental
Investigational medicinal product name	Mometasone furoate nasal spray
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray
Routes of administration	Nasal use

Dosage and administration details:

Mometasone furoate (MFNS) 50 µg spray device. For participants aged 3 to 11 years: one spray per nostril once daily (100 µg/day) in the morning for up to 24 weeks and for participant aged 12 to 15 years: 2 sprays per nostril once daily (200 µg/day) in the morning for up to 24 weeks.

Number of subjects in period 1	Mometasone furoate nasal spray
Started	80
Completed	76
Not completed	4
Adverse event, non-fatal	1
'Laboratory adverse event '	1
Met discontinuation criteria	1
Moved (relocation)	1

Baseline characteristics

Reporting groups	
Reporting group title	Treatment Period
Reporting group description:	
Mometasone furoate (MFNS) 50 µg spray device. For participants aged 3 to 11 years: one spray per nostril once daily (100 µg/day) in the morning for up to 24 weeks and for participant aged 12 to 15 years: 2 sprays per nostril once daily (200 µg/day) in the morning for up to 24 weeks.	

Reporting group values	Treatment Period	Total	
Number of subjects	80	80	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	56	56	
Adolescents (12-17 years)	24	24	
Adults (18-64 years)	0	0	
From 65-84 years	0	0	
85 years and over	0	0	
Age continuous Units: years			
arithmetic mean	9.2		
standard deviation	± 3.4	-	
Gender categorical Units: Subjects			
Female	26	26	
Male	54	54	

End points

End points reporting groups

Reporting group title	Mometasone furoate nasal spray

Reporting group description:

Mometasone furoate (MFNS) 50 µg spray device. For participants aged 3 to 11 years: one spray per nostril once daily (100 µg/day) in the morning for up to 24 weeks and for participant aged 12 to 15 years: 2 sprays per nostril once daily (200 µg/day) in the morning for up to 24 weeks.

Primary: Number of Participants With Adverse Events and Adverse Drug Reactions

End point title	Number of Participants With Adverse Events and Adverse Drug Reactions[1]

End point description:

An adverse event (AE) is defined as any unfavorable and unintended sign including an abnormal laboratory finding, symptom or disease associated with the use of a medical treatment or procedure, regardless of whether it is considered related to the medical treatment or procedure, that occurs during the course of the study. Adverse drug reactions are all noxious and unintended responses to a medicinal product related to any dose.

End point type	Primary

End point timeframe:

Up to 28 weeks

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 was performed with this primary endpoint as there was only a single study arm and the data was in the form of number of participants with no statistical analysis.

End point values	Mometasone furoate nasal spray			
Subject group type	Reporting group			
Number of subjects analysed	80			
Units: Participants				
Number with Adverse Events	76			
Number with Adverse Drug Reactions	18			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in the Total Nasal Symptom Score

End point title	Change From Baseline in the Total Nasal Symptom Score

End point description:

Total nasal symptom score was a composite of 4 symptoms (sneezing, rhinorrhea, nasal congestion, and nasal itching). Each symptom was scored on a scale of 0 = none, 1 = mild, 2 = moderate, and 3 = severe for a total score ranging from 0 to 12. A higher score indicates more severe symptoms.

End point type	Secondary

End point timeframe:

Baseline and Weeks 2, 4, 8, 12, 16, 20, and 24 (or discontinuation)

End point values	Mometasone furoate nasal spray			
Subject group type	Reporting group			
Number of subjects analysed	80			
Units: Units on a scale				
arithmetic mean (standard error)				
Week 2, N=80	-3.1 (± 0.3)			
Week 4, N=79	-3.9 (± 0.3)			
Week 8, N=79	-4.4 (± 0.3)			
Week 12, N=77	-4.5 (± 0.3)			
Week 16, N=72	-4.9 (± 0.3)			
Week 20, N=70	-5 (± 0.3)			
Week 24, N=69	-4.8 (± 0.3)			
Week 24 or discontinuation, N=80	-4.9 (± 0.3)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: Up to 214 days	
Assessment type	Systematic
Dictionary used	
Dictionary name	MedDRA
Dictionary version	13.0
Reporting groups	
Reporting group title	MFNS
Reporting group description: MFNS 50 µg spray device. For participants aged 3 to 11 years: one spray per nostril once daily (100 µg/day) in the morning for up to 24 weeks and for participant aged 12 to 15 years: 2 sprays per nostril once daily (200 µg/day) in the morning for up to 24 weeks.	

Serious adverse events	MFNS		
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 80 (1.25%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Gastrointestinal disorders			
Inguinal hernia			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	MFNS		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	72 / 80 (90.00%)		
Investigations			
Blood cortisol decreased			
subjects affected / exposed	27 / 80 (33.75%)		
occurrences (all)	30		
General disorders and administration site conditions			
Pyrexia			

subjects affected / exposed	13 / 80 (16.25%)		
occurrences (all)	17		
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	6 / 80 (7.50%)		
occurrences (all)	9		
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	8 / 80 (10.00%)		
occurrences (all)	12		
Epistaxis			
subjects affected / exposed	24 / 80 (30.00%)		
occurrences (all)	69		
Skin and subcutaneous tissue disorders			
Heat rash			
subjects affected / exposed	6 / 80 (7.50%)		
occurrences (all)	7		
Infections and infestations			
Acute sinusitis			
subjects affected / exposed	9 / 80 (11.25%)		
occurrences (all)	15		
Acute tonsillitis			
subjects affected / exposed	7 / 80 (8.75%)		
occurrences (all)	8		
Bronchitis			
subjects affected / exposed	10 / 80 (12.50%)		
occurrences (all)	17		
Nasopharyngitis			
subjects affected / exposed	41 / 80 (51.25%)		
occurrences (all)	73		
Pharyngitis			
subjects affected / exposed	11 / 80 (13.75%)		
occurrences (all)	12		
Upper respiratory tract infection			
subjects affected / exposed	5 / 80 (6.25%)		
occurrences (all)	6		

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