Clinical trial results:
Efficacy and Safety of Concurrent Administration of Mometasone Furoate Nasal Spray (MFNS) and Oxymetazoline Nasal Spray Administered Once Daily (QD) vs. Oxymetazoline Twice Daily (BID), Mometasone Furoate QD, and Placebo in the Treatment of Subjects with Seasonal Allergic Rhinitis

Summary

EudraCT number	2014-004924-23
Trial protocol	Outside EU/EEA
Global end of trial date	15 February 2008

Results information

Result version number	v1 (current)
This version publication date	08 March 2016
First version publication date	17 July 2015

Trial information

Trial identification

Sponsor protocol code	P04500

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00552110
WHO universal trial number (UTN)	-
Other trial identifiers	Merck Registration Number: MK-0887-105

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	15 February 2008
Is this the analysis of the primary completion data?	Yes
Primary completion date	15 February 2008
Global end of trial reached?	Yes
Global end of trial date	15 February 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 evaluate the efficacy of the combination of mometasone furoate nasal spray (MFNS) and oxymetazoline nasal spray (OXY) given together once a day (QD) in treating participants with seasonal allergic rhinitis (SAR) in relieving symptoms including 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	24 July 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	United States: 707
Worldwide total number of subjects	707
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)	42
Adults (18-64 years)	651
From 65 to 84 years	14
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

1329 participants were screened for this study at 54 centers in the US.

Pre-assignment

Screening details:

707 participants were randomized to Combination1, Combination3, Mometasone, Oxymetazoline, or Placebo (All Randomized Population). The Intent-To-Treat (ITT) population included all randomized participants who had taken at least one dose of study drug.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Combination1

Arm description:

Morning (AM): Mometasone Furoate nasal spray (MFNS) 2 sprays/nostril plus oxymetazoline nasal spray (OXY) 1 spray/nostril. Evening (PM): matching placebo to MFNS 2 sprays/nostril. Participants received treatment for 15 days.

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	Nasal spray
Routes of administration	Intranasal use

Dosage and administration details:

MFNS 50 µg/spray (2 sprays in each nostril) once daily for 15 days.

Investigational medicinal product name	Oxymetazoline Nasal Spray (OXY)
Investigational medicinal product code	
Other name	Afrin®, MK-3384, SCH 093840, Oxymetazoline
Pharmaceutical forms	Nasal spray
Routes of administration	Intranasal use

Dosage and administration details:

OXY (0.05%, 100 µL/spray), 1-3 sprays in each nostril (depending upon randomization) for 15 days.

Investigational medicinal product name	matching placebo nasal spray
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray
Routes of administration	Intranasal use

Dosage and administration details:

Matching placebo nasal spray to MFNS (2 or 3 sprays in each nostril) for 15 days depending upon randomization.

Arm title	Combination3

Arm description:

AM: MFNS 2 sprays/nostril plus OXY 3 sprays/nostril. PM: matching placebo to MFNS 2 sprays/nostril. Participants received treatment for 15 days.

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	Nasal spray
Routes of administration	Intranasal use

Dosage and administration details:

MFNS 50 µg/spray (2 sprays in each nostril) once daily for 15 days.

Investigational medicinal product name	Oxymetazoline Nasal Spray (OXY)
Investigational medicinal product code	
Other name	Afrin®, MK-3384, SCH 093840, Oxymetazoline
Pharmaceutical forms	Nasal spray
Routes of administration	Intranasal use

Dosage and administration details:

OXY (0.05%, 100 µL/spray), 1-3 sprays in each nostril (depending upon randomization) for 15 days.

Investigational medicinal product name	matching placebo nasal spray
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray
Routes of administration	Intranasal use

Dosage and administration details:

Matching placebo nasal spray to MFNS (2 or 3 sprays in each nostril) for 15 days depending upon randomization.

Arm title	Mometasone

Arm description:

AM: MFNS 2 sprays/nostril plus matching placebo to MFNS 1 spray/nostril. PM: matching placebo to MFNS 2 sprays/nostril. Participants received treatment for 15 days.

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

Dosage and administration details:

MFNS 50 µg/spray (2 sprays in each nostril) once daily for 15 days.

Investigational medicinal product name	matching placebo nasal spray
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray
Routes of administration	Intranasal use

Dosage and administration details:

Matching placebo nasal spray to MFNS (2 or 3 sprays in each nostril) for 15 days depending upon randomization.

Arm title	Oxymetazoline

Arm description:

AM: matching placebo to MFNS 2 sprays/nostril plus OXY 2 sprays/nostril. PM: OXY 2 sprays/nostril. Participants received treatment for 15 days.

Arm type	Active comparator

Investigational medicinal product name	matching placebo nasal spray
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray
Routes of administration	Intranasal use

Dosage and administration details:

Matching placebo nasal spray to MFNS (2 or 3 sprays in each nostril) for 15 days depending upon randomization.

Investigational medicinal product name	Oxymetazoline Nasal Spray (OXY)
Investigational medicinal product code	
Other name	Afrin®, MK-3384, SCH 093840, Oxymetazoline
Pharmaceutical forms	Nasal spray
Routes of administration	Intranasal use

Dosage and administration details:

OXY (0.05%, 100 µL/spray), 1-3 sprays in each nostril (depending upon randomization) for 15 days.

Arm title	Placebo

Arm description:

AM: matching placebo to MFNS 2 sprays/nostril plus matching placebo to MFNS 3 sprays/nostril. PM: matching placebo to MFNS 2 sprays/nostril. Participants received treatment for 15 days.

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

Dosage and administration details:

Matching placebo nasal spray to MFNS (2 or 3 sprays in each nostril) for 15 days depending upon randomization.

Number of subjects in period 1	Combination1	Combination3	Mometasone
Started	146	139	139
Treated (Intention To Treat [ITT])	145	139	139
Completed	142	134	137
Not completed	4	5	2
Withdrawn per Sponsor	-	1	-
Consent withdrawn by subject	-	2	-
Serious or Life-Threatening AE	-	-	1
Increased Blood Pressure at Visit 2	-	-	-
Failed to Comply With Study Requirements	1	1	1
Nonserious Adverse Event (AE)	1	-	-
Use of Prohibited Medication	1	1	-
Lost to follow-up	-	-	-
Delay of Study due to Relabeling	-	-	-
Lack of efficacy	1	-	-

Number of subjects in period 1	Oxymetazoline	Placebo
Started	141	142
Treated (Intention To Treat [ITT])	140	142
Completed	133	133
Not completed	8	9
Withdrawn per Sponsor	-	1
Consent withdrawn by subject	3	2
Serious or Life-Threatening AE	-	-
Increased Blood Pressure at Visit 2	1	-
Failed to Comply With Study Requirements	-	1
Nonserious Adverse Event (AE)	1	-
Use of Prohibited Medication	-	-
Lost to follow-up	1	1
Delay of Study due to Relabeling	1	-
Lack of efficacy	1	4

Baseline characteristics

Reporting groups	
Reporting group title	Combination1
Reporting group description:	
Morning (AM): Mometasone Furoate nasal spray (MFNS) 2 sprays/nostril plus oxymetazoline nasal spray (OXY) 1 spray/nostril. Evening (PM): matching placebo to MFNS 2 sprays/nostril. Participants received treatment for 15 days.	
Reporting group title	Combination3
Reporting group description:	
AM: MFNS 2 sprays/nostril plus OXY 3 sprays/nostril. PM: matching placebo to MFNS 2 sprays/nostril. Participants received treatment for 15 days.	
Reporting group title	Mometasone
Reporting group description:	
AM: MFNS 2 sprays/nostril plus matching placebo to MFNS 1 spray/nostril. PM: matching placebo to MFNS 2 sprays/nostril. Participants received treatment for 15 days.	
Reporting group title	Oxymetazoline
Reporting group description:	
AM: matching placebo to MFNS 2 sprays/nostril plus OXY 2 sprays/nostril. PM: OXY 2 sprays/nostril. Participants received treatment for 15 days.	
Reporting group title	Placebo
Reporting group description:	
AM: matching placebo to MFNS 2 sprays/nostril plus matching placebo to MFNS 3 sprays/nostril. PM: matching placebo to MFNS 2 sprays/nostril. Participants received treatment for 15 days.	

Reporting group values	Combination1	Combination3	Mometasone
Number of subjects	146	139	139
Age Categorical			
Data reported for all randomized participants.			
Units: participants			
<=18 years	8	12	5
Between 18 and 64 years	136	124	132
>=65 years	2	3	2
Gender, Male/Female			
Data reported for all randomized participants.			
Units: participants			
Female	93	93	101
Male	53	46	38

Reporting group values	Oxymetazoline	Placebo	Total
Number of subjects	141	142	707
Age Categorical			
Data reported for all randomized participants.			
Units: participants			
<=18 years	5	12	42
Between 18 and 64 years	132	127	651
>=65 years	4	3	14
Gender, Male/Female			
Data reported for all randomized participants.			
Units: participants			
Female	96	89	472

Male	45	53	235

End points

End points reporting groups

Reporting group title	Combination1
Reporting group description:	
Morning (AM): Mometasone Furoate nasal spray (MFNS) 2 sprays/nostril plus oxymetazoline nasal spray (OXY) 1 spray/nostril. Evening (PM): matching placebo to MFNS 2 sprays/nostril. Participants received treatment for 15 days.	
Reporting group title	Combination3
Reporting group description:	
AM: MFNS 2 sprays/nostril plus OXY 3 sprays/nostril. PM: matching placebo to MFNS 2 sprays/nostril. Participants received treatment for 15 days.	
Reporting group title	Mometasone
Reporting group description:	
AM: MFNS 2 sprays/nostril plus matching placebo to MFNS 1 spray/nostril. PM: matching placebo to MFNS 2 sprays/nostril. Participants received treatment for 15 days.	
Reporting group title	Oxymetazoline
Reporting group description:	
AM: matching placebo to MFNS 2 sprays/nostril plus OXY 2 sprays/nostril. PM: OXY 2 sprays/nostril. Participants received treatment for 15 days.	
Reporting group title	Placebo
Reporting group description:	
AM: matching placebo to MFNS 2 sprays/nostril plus matching placebo to MFNS 3 sprays/nostril. PM: matching placebo to MFNS 2 sprays/nostril. Participants received treatment for 15 days.	

Primary: Change from baseline in AM/PM instantaneous total nasal symptom score (NOW TNSS) averaged over Days 1 to 15

End point title	Change from baseline in AM/PM instantaneous total nasal symptom score (NOW TNSS) averaged over Days 1 to 15
End point description:	
Participants scored severity of rhinorrhea, nasal congestion/stuffiness, nasal itching, and sneezing at the time of evaluation (NOW) using an ordinal scale from 0 = none to 3 = severe. Evaluations were performed daily in the morning (AM) and evening (PM). For each evaluation, the four individual symptom scores were summed to a TNSS (range 0-12), which was then averaged for a single score across the 15 day treatment period. The ITT population, including all randomized participants who had taken at least one dose of study drug, was used for analysis.	
End point type	Primary
End point timeframe:	
Baseline and 15 days of treatment	

End point values	Combination1	Combination3	Mometasone	Oxymetazoline
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	145	138	139	139
Units: units on a scale				
least squares mean (standard error)	-3.29 (± 0.209)	-3.36 (± 0.216)	-2.97 (± 0.213)	-2.44 (± 0.215)

End point values	Placebo			
Subject group type	Reporting group			
Number of subjects analysed	140			
Units: units on a scale				
least squares mean (standard error)	-1.9 (± 0.209)			

Statistical analyses

Statistical analysis title	NOW TNSS Days 1-15: Combination3 vs. Oxymetazoline

Statistical analysis description:

Null hypothesis: the concurrent administration of MFNS and OXY once daily has the same mean change from baseline in AM/PM NOW TNSS as that of OXY twice daily.

Comparison groups	Combination3 v Oxymetazoline
Number of subjects included in analysis	277
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	ANCOVA
Parameter estimate	LS Means Difference
Point estimate	-0.92
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.45
upper limit	-0.38

Statistical analysis title	NOW TNSS Days 1-15: Combination1 vs. Oxymetazoline

Statistical analysis description:

Null hypothesis: the concurrent administration of MFNS and OXY once daily has the same mean change from baseline in AM/PM NOW TNSS as that of OXY twice daily.
Power calculation: The target randomization of 875 subjects (175 subjects per treatment arm) was needed to detect a treatment difference of 0.8 point or more in change from baseline in AM/PM NOW TNSS, with a two-sided alpha of 0.05 and 90% power, assuming a pooled standard deviation of 2.3 points.

Comparison groups	Combination1 v Oxymetazoline
Number of subjects included in analysis	284
Analysis specification	Pre-specified
Analysis type	other[1]
P-value	= 0.002 [2]
Method	ANCOVA
Parameter estimate	LS Means Difference
Point estimate	-0.85
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.38
upper limit	-0.33

Notes:

[1] - Analysis of Covariance (ANCOVA); classification variables: treatment, center, dosing sequence (stratification variable); covariate: baseline score

[2] - Multiplicity for multiple treatment comparisons was not adjusted.

Statistical analysis title	NOW TNSS Days 1-15: Mometasone vs. Placebo

Statistical analysis description:

Null hypothesis: the administration of MFNS once daily has the same mean change from baseline in AM/PM NOW TNSS as that of placebo.

Comparison groups	Mometasone v Placebo
Number of subjects included in analysis	279
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	ANCOVA
Parameter estimate	LS Means Difference
Point estimate	-1.07
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.61
upper limit	-0.53

Primary: Standardized area under the curve from 0 to 4 hours [AUC(0-4 hr)] of the change from baseline to hour 4 on Day 1 in nasal congestion score

End point title	Standardized area under the curve from 0 to 4 hours [AUC(0-4 hr)] of the change from baseline to hour 4 on Day 1 in nasal congestion score

End point description:

Participants scored the nasal congestion/stuffiness symptom using an ordinal scale from 0 = none to 3 = severe. Baseline was the average of the scores assessed every 15 minutes for 1 hour prior to dosing on Day 1. After dosing on Day 1, congestion was scored every 15 minutes for the 1st hour and every 30 minutes for the next 3 hours. Area under the curve (AUC) was calculated using the trapezoid rule, then standardization achieved by dividing the calculation by 4 hours. Treatment comparisons were examined using the standardized AUC(0-4 hr) of the change from baseline to hour 4 on Day 1. The ITT population, including all randomized participants who had taken at least one dose of study drug, was used for analysis.

End point type	Primary

End point timeframe:

From Baseline to hour 4 on Day 1

End point values	Combination1	Combination3	Mometasone	Oxymetazoline
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	144	138	139	139
Units: units on a scale				
least squares mean (standard error)	-0.8 (± 0.056)	-0.92 (± 0.057)	-0.63 (± 0.057)	-1.06 (± 0.057)

End point values	Placebo			
Subject group type	Reporting group			
Number of subjects analysed	140			
Units: units on a scale				
least squares mean (standard error)	-0.57 (± 0.056)			

Statistical analyses

Statistical analysis title	AUC0-4 on Day 1: Combination1 vs. Mometasone

Statistical analysis description:

Null hypothesis: the concurrent administration of MFNS and OXY once daily has the same standardized AUC(0-4 hr) of the change from baseline in nasal congestion score as that of MFNS once daily.

Comparison groups	Combination1 v Mometasone
Number of subjects included in analysis	283
Analysis specification	Pre-specified
Analysis type	other[3]
P-value	= 0.021 [4]
Method	ANCOVA
Parameter estimate	LS Means Difference
Point estimate	-0.17
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.31
upper limit	-0.03

Notes:

[3] - ANCOVA; classification variables: treatment, center, dosing sequence (stratification variable); covariate: baseline score

[4] - Multiplicity for multiple treatment comparisons was not adjusted.

Statistical analysis title	AUC0-4 on Day 1: Combination3 vs. Mometasone

Statistical analysis description:

Null hypothesis: the concurrent administration of MFNS and OXY once daily has the same standardized AUC (0-4hr) of the change from baseline in nasal congestion score as that of MFNS once daily

Comparison groups	Combination3 v Mometasone
Number of subjects included in analysis	277
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	ANCOVA
Parameter estimate	LS Means Difference
Point estimate	-0.29

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.43
upper limit	-0.14

Statistical analysis title	AUC0-4 on Day 1: Oxymetazoline vs. Placebo

Statistical analysis description:

Null hypothesis: the administration of OXY twice daily has the same standardized AUC(0-4 hr) of the change from baseline in nasal congestion score as that of placebo

Comparison groups	Oxymetazoline v Placebo
Number of subjects included in analysis	279
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	ANCOVA
Parameter estimate	LS Means Difference
Point estimate	-0.49
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.63
upper limit	-0.35

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From Treatment Day 1 through 30 days post study completion/discontinuation (up to 52 days total)

Adverse event reporting additional description:

The ITT population, which included all randomized participants who had taken ≥1 dose of study medication, was used for safety analyses.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	10.1

Reporting groups

Reporting group title	Combination1

Reporting group description:

Morning (AM): Mometasone Furoate nasal spray (MFNS) 2 sprays/nostril plus oxymetazoline nasal spray (OXY) 1 spray/nostril. Evening (PM): matching placebo to MFNS 2 sprays/nostril. Participants received treatment for 15 days.

Reporting group title	Combination3

Reporting group description:

AM: MFNS 2 sprays/nostril plus OXY 3 sprays/nostril. PM: matching placebo to MFNS 2 sprays/nostril. Participants received treatment for 15 days.

Reporting group title	Mometasone

Reporting group description:

AM: MFNS 2 sprays/nostril plus matching placebo to MFNS 1 spray/nostril. PM: matching placebo to MFNS 2 sprays/nostril. Participants received treatment for 15 days.

Reporting group title	Oxymetazoline

Reporting group description:

AM: matching placebo to MFNS 2 sprays/nostril plus OXY 2 sprays/nostril. PM: OXY 2 sprays/nostril. Participants received treatment for 15 days.

Reporting group title	Placebo

Reporting group description:

AM: matching placebo to MFNS 2 sprays/nostril plus matching placebo to MFNS 3 sprays/nostril. PM: matching placebo to MFNS 2 sprays/nostril. Participants received treatment for 15 days.

Serious adverse events	Combination1	Combination3	Mometasone
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 145 (0.00%)	0 / 139 (0.00%)	1 / 139 (0.72%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Gastrointestinal disorders			
Gastrooesophageal Reflux Disease			
subjects affected / exposed	0 / 145 (0.00%)	0 / 139 (0.00%)	0 / 139 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal Haemorrhage			

subjects affected / exposed	0 / 145 (0.00%)	0 / 139 (0.00%)	1 / 139 (0.72%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Oxymetazoline	Placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 140 (0.00%)	1 / 142 (0.70%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			
Gastrointestinal disorders			
Gastrooesophageal Reflux Disease			
subjects affected / exposed	0 / 140 (0.00%)	1 / 142 (0.70%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal Haemorrhage			
subjects affected / exposed	0 / 140 (0.00%)	0 / 142 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Combination1	Combination3	Mometasone
Total subjects affected by non-serious adverse events			
subjects affected / exposed	7 / 145 (4.83%)	5 / 139 (3.60%)	10 / 139 (7.19%)
Nervous system disorders			
Headache			
subjects affected / exposed	7 / 145 (4.83%)	5 / 139 (3.60%)	10 / 139 (7.19%)
occurrences (all)	9	5	11

Non-serious adverse events	Oxymetazoline	Placebo	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	7 / 140 (5.00%)	8 / 142 (5.63%)	
Nervous system disorders			
Headache			
subjects affected / exposed	7 / 140 (5.00%)	8 / 142 (5.63%)	
occurrences (all)	8	8	

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.

Subject symptom data were not collected during the post-treatment period. Thus, daily diary data for rebound congestion was not analyzed.

Notes: