



Clinical trial results:

A Comparison of Fluticasone Furoate Nasal Spray versus Oral Fexofenadine in the treatment of seasonal allergic rhinitis

Summary

EudraCT number	2015-004873-34
Trial protocol	Outside EU/EEA
Global end of trial date	18 November 2007

Results information

Result version number	v1 (current)
This version publication date	22 January 2017
First version publication date	22 January 2017

Trial information

Trial identification

Sponsor protocol code	FFU109047
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	GlaxoSmithKline
Sponsor organisation address	980 Great West Road, Brentford, Middlesex, United Kingdom,
Public contact	GSK Response Center, GlaxoSmithKline, 1 866-435-7343,
Scientific contact	GSK Response Center, GlaxoSmithKline, 1 866-435-7343,

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	10 January 2008
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	18 November 2007
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

TBD

Protection of trial subjects:

Not applicable.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	10 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	United States: 680
Worldwide total number of subjects	680
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)	82
Adults (18-64 years)	591
From 65 to 84 years	7
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Forty-two sites in the mid-western United States screened 1008 subjects for this study. Any subject assigned a subjects number but not randomised was considered a screening failure. Of the 1008 subjects, 328 subjects (33%) were screening failures.

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Subjects received vehicle placebo nasal spray and oral placebo capsule once daily for 2 weeks.

Arm type	Placebo
Investigational medicinal product name	Placebo Capsule
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Once daily for 2 weeks

Investigational medicinal product name	Placebo Nasal Spray
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, suspension
Routes of administration	Nasal use

Dosage and administration details:

Once daily for 2 weeks

Arm title	Fluticasone Furoate 110 mcg
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Arm description:

Subjects received Fluticasone Furoate nasal spray 110 microgram and oral placebo capsule administered once daily for 2 weeks.

Arm type	Experimental
Investigational medicinal product name	Fluticasone Furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, suspension
Routes of administration	Nasal use

Dosage and administration details:

110 microgram (mcg) once daily for 2 weeks

Investigational medicinal product name	Placebo Capsule
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use
Dosage and administration details:	
Once daily for 2 weeks	
Arm title	Fexofenadine 180 mg

Arm description:

Subjects received overencapsulated fexofenadine 180mg oral tablet and vehicle placebo nasal spray once daily for 2 weeks.

Arm type	Active comparator
Investigational medicinal product name	Fexofenadine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

180 milligram (mg) once daily for 2 weeks

Investigational medicinal product name	Placebo Nasal Spray
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, suspension
Routes of administration	Nasal use

Dosage and administration details:

Once daily for 2 weeks

Number of subjects in period 1	Placebo	Fluticasone Furoate 110 mcg	Fexofenadine 180 mg
Started	229	224	227
Completed	219	209	214
Not completed	10	15	13
Randomized in error	-	1	1
Sponsor Terminated Study	1	-	1
Logpad compliance <80%	1	-	-
Non-compliance with eDiary	4	1	1
Consent withdrawn by subject	1	1	2
Subject unable to swallow capsule	1	-	1
Adverse event, non-fatal	1	2	1
Non-compliance	-	2	2
Subject in jail	-	1	-
Outside pollen area more than 48 hours	-	1	-
Declining pollen counts	-	1	1
Subject took disallowed drug	-	-	1

Protocol deviation	1	5	2
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Baseline characteristics

Reporting groups

Reporting group title	Placebo
Reporting group description: Subjects received vehicle placebo nasal spray and oral placebo capsule once daily for 2 weeks.	
Reporting group title	Fluticasone Furoate 110 mcg
Reporting group description: Subjects received Fluticasone Furoate nasal spray 110 microgram and oral placebo capsule administered once daily for 2 weeks.	
Reporting group title	Fexofenadine 180 mg
Reporting group description: Subjects received overencapsulated fexofenadine 180mg oral tablet and vehicle placebo nasal spray once daily for 2 weeks.	

Reporting group values	Placebo	Fluticasone Furoate 110 mcg	Fexofenadine 180 mg
Number of subjects	229	224	227
Age categorical Units: Subjects			

Age continuous			
Age continuous description			
Units: years			
arithmetic mean	34.8	34	34.3
standard deviation	± 12.71	± 13.55	± 13.66
Gender categorical			
Gender categorical description			
Units: Subjects			
Female	139	152	135
Male	90	72	92
Race/Ethnicity, Customized			
Units: Subjects			
White	181	189	181
African American	40	29	42
Other	8	6	4

Reporting group values	Total		
Number of subjects	680		
Age categorical Units: Subjects			

Age continuous			
Age continuous description			
Units: years			
arithmetic mean			
standard deviation	-		

Gender categorical			
Gender categorical description			
Units: Subjects			
Female	426		
Male	254		
Race/Ethnicity, Customized			
Units: Subjects			
White	551		
African American	111		
Other	18		

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description: Subjects received vehicle placebo nasal spray and oral placebo capsule once daily for 2 weeks.	
Reporting group title	Fluticasone Furoate 110 mcg
Reporting group description: Subjects received Fluticasone Furoate nasal spray 110 microgram and oral placebo capsule administered once daily for 2 weeks.	
Reporting group title	Fexofenadine 180 mg
Reporting group description: Subjects received overencapsulated fexofenadine 180mg oral tablet and vehicle placebo nasal spray once daily for 2 weeks.	

Primary: Mean Change from Baseline in the Nighttime Symptom Score (NSS)

End point title	Mean Change from Baseline in the Nighttime Symptom Score (NSS)
End point description: Questions include: 1. Nasal congestion on awakening (Score: 0=none, 1=mild, 2=moderate, 3=severe); 2. Difficulty going to sleep (Score: 0=not at all, 1=little, 2=moderately, 3=very); 3. Nighttime awakenings (Score: 0=not at all, 1=once, 2=more than once, 3=felt like awake all night). The sum of the ratings for the three items comprises the NSS. The Intent-to-Treat (ITT) population included all subjects randomized to double-blind treatment. This population formed the basis for all summaries of demographic, background, efficacy, and safety data.	
End point type	Primary
End point timeframe: Baseline and Weeks 1-2	

End point values	Placebo	Fluticasone Furoate 110 mcg	Fexofenadine 180 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	228 ^[1]	224 ^[2]	226 ^[3]	
Units: Score on a Scale				
arithmetic mean (standard error)	-2.3 (± 0.11)	-3.1 (± 0.12)	-2.2 (± 0.12)	

Notes:

[1] - ITT population

[2] - ITT population

[3] - ITT population

Statistical analyses

Statistical analysis title	Statistical analysis 1
Statistical analysis description: The primary efficacy measure, mean change from baseline over the two-week treatment period in NSS compared between fluticasone furoate and fexofenadine, was assessed at a significance level of $\alpha=0.05$. If the null hypothesis of this comparison was rejected, then the secondary measures were subject to hypothesis testing. The study was powered at 90%. Mean Difference = Mean Change in Fluticasone Furoate - Mean Change in Fexofenadine.	

Comparison groups	Fluticasone Furoate 110 mcg v Fexofenadine 180 mg
Number of subjects included in analysis	450
Analysis specification	Pre-specified
Analysis type	other ^[4]
P-value	< 0.001 ^[5]
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.2
upper limit	-0.6
Variability estimate	Standard error of the mean
Dispersion value	0.16

Notes:

[4] - Symptom scores were grouped in 3 families: nasal, ocular, instantaneous. Within each family, results of hypothesis tests were adjusted using Hochberg's method.

[5] - Symptom scores were grouped in 3 families: nasal, ocular, instantaneous. Within each family, results of hypothesis tests were adjusted using Hochberg's method.

Statistical analysis title	Statistical analysis 2
Statistical analysis description:	
Mean Difference = Mean Change in Fluticasone Furoate - Mean Change in Placebo	
Comparison groups	Placebo v Fluticasone Furoate 110 mcg
Number of subjects included in analysis	452
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.1
upper limit	-0.4
Variability estimate	Standard error of the mean
Dispersion value	0.16

Statistical analysis title	Statistical analysis 3
Statistical analysis description:	
Mean Difference = Mean Change in Fexofenadine - Mean Change in Placebo.	
Comparison groups	Placebo v Fexofenadine 180 mg

Number of subjects included in analysis	454
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.374
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	0.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.2
upper limit	0.5
Variability estimate	Standard error of the mean
Dispersion value	0.16

Secondary: Mean Change from Baseline in Nighttime Reflective Total Nasal Symptom Score (N-rTNSS)

End point title	Mean Change from Baseline in Nighttime Reflective Total Nasal Symptom Score (N-rTNSS)
End point description:	Subjects assessed four nasal symptoms (rhinorrhea, nasal congestion, nasal itching, and sneezing). The sum of the four nasal symptoms comprised the total nasal symptom score (TNSS). Reflective rating represented symptoms over preceding 12 hours. Scores: 0=symptoms not present, 1=mild severity, 2=moderate severity, 3=severe.
End point type	Secondary
End point timeframe:	Baseline and Weeks 1-2

End point values	Placebo	Fluticasone Furoate 110 mcg	Fexofenadine 180 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	228 ^[6]	224 ^[7]	226 ^[8]	
Units: Score on a Scale				
arithmetic mean (standard error)	-2.9 (± 0.15)	-4.1 (± 0.17)	-2.9 (± 0.16)	

Notes:

[6] - ITT population

[7] - ITT population

[8] - ITT population

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change from Baseline in Daytime Reflective Total Nasal Symptom Score (D-rTNSS)

End point title	Mean Change from Baseline in Daytime Reflective Total Nasal Symptom Score (D-rTNSS)
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End point description:

Subjects assessed four nasal symptoms (rhinorrhea, nasal congestion, nasal itching, and sneezing). The sum of the four nasal symptoms comprised the total nasal symptom score. Reflective rating represented symptoms over preceding 12 hours. Scores: 0=symptoms not present, 1=mild severity, 2=moderate severity, 3=severe.

End point type	Secondary
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End point timeframe:

Baseline and Weeks 1-2

End point values	Placebo	Fluticasone Furoate 110 mcg	Fexofenadine 180 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	228 ^[9]	224 ^[10]	226 ^[11]	
Units: Score on a Scale				
arithmetic mean (standard error)	-3 (± 0.15)	-4.2 (± 0.18)	-2.9 (± 0.16)	

Notes:

[9] - ITT population

[10] - ITT population

[11] - ITT population

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change from Baseline in 24 Hour Reflective Total Nasal Symptom Score (24 Hour rTNSS)

End point title	Mean Change from Baseline in 24 Hour Reflective Total Nasal Symptom Score (24 Hour rTNSS)
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End point description:

Subjects assessed four nasal symptoms (rhinorrhea, nasal congestion, nasal itching, and sneezing). The sum of the four nasal symptoms comprised the total nasal symptom score. Reflective rating represented symptoms over preceding 12 hours. Scores: 0=symptoms not present, 1=mild severity, 2=moderate severity, 3=severe.

End point type	Secondary
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End point timeframe:

Baseline and Weeks 1-2

End point values	Placebo	Fluticasone Furoate 110 mcg	Fexofenadine 180 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	228 ^[12]	224 ^[13]	226 ^[14]	
Units: Score on a Scale				
arithmetic mean (standard error)	-2.8 (± 0.14)	-4.1 (± 0.18)	-2.8 (± 0.16)	

Notes:

[12] - ITT population

[13] - ITT population

[14] - ITT population

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change From Baseline in Nighttime Reflective Total Ocular Symptom Score (N-rTOSS)

End point title	Mean Change From Baseline in Nighttime Reflective Total Ocular Symptom Score (N-rTOSS)
End point description: Subjects assessed three ocular symptoms (itching/ burning eyes, tearing/watering eyes, and eye redness). The sum of the 3 ocular symptoms comprised the total ocular symptom score (TOSS). Reflective rating represented symptoms over preceding 12 hours. Scores: 0=symptoms not present, 1=mild severity, 2=moderate severity, 3=severe.	
End point type	Secondary
End point timeframe: Baseline and Weeks 1-2	

End point values	Placebo	Fluticasone Furoate 110 mcg	Fexofenadine 180 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	228 ^[15]	224 ^[16]	226 ^[17]	
Units: Score on a Scale				
arithmetic mean (standard error)	-2.3 (± 0.13)	-2.7 (± 0.14)	-2.2 (± 0.13)	

Notes:

[15] - ITT population

[16] - ITT population

[17] - ITT population

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change From Baseline in Daytime Reflective Total Ocular Symptom Score (D-rTOSS)

End point title	Mean Change From Baseline in Daytime Reflective Total Ocular Symptom Score (D-rTOSS)
End point description: Subjects assessed three ocular symptoms (itching/ burning eyes, tearing/watering eyes, and eye redness). The sum of the 3 ocular symptoms comprised the total ocular symptom score. Reflective rating represented symptoms over preceding 12 hours. Scores: 0=symptoms not present, 1=mild severity, 2=moderate severity, 3=severe.	
End point type	Secondary
End point timeframe: Baseline and Weeks 1-2	

End point values	Placebo	Fluticasone Furoate 110 mcg	Fexofenadine 180 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	228 ^[18]	224 ^[19]	226 ^[20]	
Units: Score on a Scale				
arithmetic mean (standard error)	-2.5 (± 0.13)	-2.9 (± 0.14)	-2.4 (± 0.13)	

Notes:

[18] - ITT population

[19] - ITT population

[20] - ITT population

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change From Baseline in 24 Hour Reflective Total Ocular Symptoms Score (rTOSS)

End point title	Mean Change From Baseline in 24 Hour Reflective Total Ocular Symptoms Score (rTOSS)
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End point description:

Subjects assessed three ocular symptoms (itching/ burning eyes, tearing/watering eyes, and eye redness). The sum of the 3 ocular symptoms comprised the total ocular symptom score. Reflective rating represented symptoms over preceding 12 hours. Scores: 0=symptoms not present, 1=mild severity, 2=moderate severity, 3=severe.

End point type	Secondary
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End point timeframe:

Baseline and Weeks 1-2

End point values	Placebo	Fluticasone Furoate 110 mcg	Fexofenadine 180 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	228 ^[21]	224 ^[22]	226 ^[23]	
Units: Score on a Scale				
arithmetic mean (standard error)	-2.3 (± 0.13)	-2.7 (± 0.14)	-2.2 (± 0.13)	

Notes:

[21] - ITT population

[22] - ITT population

[23] - ITT population

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change From Baseline in Pre-Dose Instantaneous Total Nasal Symptom Score (iTNSS)

End point title	Mean Change From Baseline in Pre-Dose Instantaneous Total Nasal Symptom Score (iTNSS)
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End point description:

Subjects assessed four nasal symptoms (rhinorrhea, nasal congestion, nasal itching, and sneezing). The sum of the four nasal symptoms comprised the total nasal symptom score. Instantaneous rating represented symptoms at the time of the assessment. Scores: 0=symptoms not present, 1=mild

severity, 2=moderate severity, 3=severe.

End point type	Secondary
End point timeframe:	
Baseline and Weeks 1-2	

End point values	Placebo	Fluticasone Furoate 110 mcg	Fexofenadine 180 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	228 ^[24]	224 ^[25]	226 ^[26]	
Units: Score on a Scale				
arithmetic mean (standard error)	-2.8 (± 0.15)	-4.1 (± 0.18)	-2.7 (± 0.17)	

Notes:

[24] - ITT population

[25] - ITT population

[26] - ITT population

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change From Baseline in Pre-Dose Instantaneous Total Ocular Symptom Score (iTOSS)

End point title	Mean Change From Baseline in Pre-Dose Instantaneous Total Ocular Symptom Score (iTOSS)
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End point description:

Subjects assessed three ocular symptoms (itching/ burning eyes, tearing/watering eyes, and eye redness). The sum of the three ocular symptoms comprised the total ocular Symptom score. Instantaneous rating represented symptoms at the time of the assessment. Scores: 0=symptoms not present, 1=mild severity, 2=moderate severity, 3=severe.

End point type	Secondary
End point timeframe:	
Baseline and Weeks 1-2	

End point values	Placebo	Fluticasone Furoate 110 mcg	Fexofenadine 180 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	228 ^[27]	224 ^[28]	226 ^[29]	
Units: Score on a Scale				
arithmetic mean (standard error)	-2.2 (± 0.13)	-2.7 (± 0.14)	-2.2 (± 0.14)	

Notes:

[27] - ITT population

[28] - ITT population

[29] - ITT population

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change from Baseline in Morning Peak Nasal Inspiratory Flow (PNIF)

End point title	Mean Change from Baseline in Morning Peak Nasal Inspiratory Flow (PNIF)
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End point description:

Subjects used a portable hand-held inspiratory flow meter to measure and record PNIF in the morning prior to taking the study medication. Three measurements were taken and the highest measurement was recorded in the electronic diary. A positive change signifies improved nasal air flow. Two subjects in the placebo group & three in the Fluticasone Furoate Nasal Spray (FFNS) group recorded no data during the two-week treatment period.

End point type	Secondary
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End point timeframe:

Baseline and Weeks 1-2

End point values	Placebo	Fluticasone Furoate 110 mcg	Fexofenadine 180 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	226 ^[30]	221 ^[31]	226 ^[32]	
Units: Score on a Scale				
arithmetic mean (standard error)	4.8 (± 1.27)	13 (± 1.61)	2.2 (± 1.21)	

Notes:

[30] - ITT population

[31] - ITT population

[32] - ITT population

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change From Baseline in Evening Peak Nasal Inspiratory Flow (PNIF)

End point title	Mean Change From Baseline in Evening Peak Nasal Inspiratory Flow (PNIF)
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End point description:

Subjects used a portable hand-held inspiratory flow meter to measure and record PNIF in the evening. Three measurements were taken and the highest measurement was recorded in the electronic diary. A positive change signifies improved nasal air flow. Two subjects in the placebo group & two in the FFNS group recorded no data during the two-week treatment period.

End point type	Secondary
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End point timeframe:

Baseline and Weeks 1-2

End point values	Placebo	Fluticasone Furoate 110 mcg	Fexofenadine 180 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	226 ^[33]	222 ^[34]	226 ^[35]	
Units: Score on a Scale				
arithmetic mean (standard error)	2.3 (± 1.38)	9.7 (± 1.73)	0.3 (± 1.37)	

Notes:

[33] - ITT population

[34] - ITT population

[35] - ITT population

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change From Baseline at Day 15 for Nocturnal Rhinoconjunctivitis Quality of Life Questionnaire (NRQLQ)

End point title	Mean Change From Baseline at Day 15 for Nocturnal Rhinoconjunctivitis Quality of Life Questionnaire (NRQLQ)
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End point description:

Subjects completed the 16-item Nocturnal Rhinoconjunctivitis Quality of Life Questionnaire to assess nocturnal rhinitis-related quality of life. The NRQLQ measures the functional problems most troublesome to patients with nocturnal allergy symptoms. Each question scored from 0-6 with higher scores indicating more nocturnal impairment.

Ten placebo subjects, six FFNS subjects, and four fexofenadine subjects had no overall NRQLQ score at endpoint, indicating either a missing score for one or more of the NRQLQ domains, a missing baseline score, or both. One additional FFNS patient had no on-treatment NRQLQ data.

End point type	Secondary
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End point timeframe:

Baseline, Day 15 or if Early Withdrawal Day

End point values	Placebo	Fluticasone Furoate 110 mcg	Fexofenadine 180 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	218 ^[36]	217 ^[37]	222 ^[38]	
Units: Score on a Scale				
arithmetic mean (standard error)	-1.4 (± 0.09)	-2 (± 0.1)	-1.4 (± 0.1)	

Notes:

[36] - ITT population

[37] - ITT population

[38] - ITT population

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

All AE data from the time of subject consent until the follow-up period (approximately 22 days) were collected.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	10.1
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Reporting groups

Reporting group title	Placebo
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Reporting group description:

Subjects received vehicle placebo nasal spray and oral placebo capsule once daily for 2 weeks.

Reporting group title	Fexofenadine 180 mg
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Reporting group description:

Subjects received overencapsulated fexofenadine 180mg oral tablet and vehicle placebo nasal spray once daily for 2 weeks.

Reporting group title	Fluticasone Furoate 110mcg
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Reporting group description:

Subjects received Fluticasone Furoate nasal spray 110 microgram and oral placebo capsule once daily for 2 weeks.

Serious adverse events	Placebo	Fexofenadine 180 mg	Fluticasone Furoate 110mcg
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 229 (0.00%)	1 / 227 (0.44%)	0 / 224 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Renal and urinary disorders			
Ureteric obstruction			
subjects affected / exposed	0 / 229 (0.00%)	1 / 227 (0.44%)	0 / 224 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Frequency threshold for reporting non-serious adverse events: 3 %

Non-serious adverse events	Placebo	Fexofenadine 180 mg	Fluticasone Furoate 110mcg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 229 (2.62%)	9 / 227 (3.96%)	10 / 224 (4.46%)
Nervous system disorders			

Headache			
subjects affected / exposed	6 / 229 (2.62%)	9 / 227 (3.96%)	10 / 224 (4.46%)
occurrences (all)	7	13	13

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