



Clinical trial results:

A Randomized, Double-Blind, Placebo- Controlled, Parallel-Group, Multi-Center Study to Assess the Efficacy of Once-Daily Fluticasone Propionate Aqueous Nasal Spray 200mcg for 14 Days on Ocular Symptoms Associated with Seasonal Allergic Rhinitis

Summary

EudraCT number	2015-001727-23
Trial protocol	Outside EU/EEA
Global end of trial date	16 February 2013

Results information

Result version number	v2 (current)
This version publication date	09 June 2017
First version publication date	08 August 2015
Version creation reason	<ul style="list-style-type: none">• Correction of full data set Eudract is showing that results have issues. checking the errors
Summary attachment (see zip file)	RH01619 (RH01619-Clinical-Study-Result-Summary.pdf)

Trial information

Trial identification

Sponsor protocol code	RH01619
-----------------------	---------

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01817790
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	GlaxoSmithKline Consumer Healthcare
Sponsor organisation address	St. George's Avenue, Weybridge, United Kingdom, KT13 0DE
Public contact	Clinical trial disclosure desk, GlaxoSmithKline Consumer Healthcare, 866 435-7343,
Scientific contact	Clinical trial disclosure desk, GlaxoSmithKline Consumer Healthcare, 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	15 May 2013
Is this the analysis of the primary completion data?	Yes
Primary completion date	16 February 2013
Global end of trial reached?	Yes
Global end of trial date	16 February 2013
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To demonstrate that a 14-day course of FP200QD is superior to placebo in relieving ocular symptoms associated with AR as determined by mean change from baseline in subject-rated reflective total ocular symptom scores (rTOSS)

Protection of trial subjects:

This study was conducted in accordance with the ethical principles that have their origin in the World Medical Association Declaration of Helsinki.

The study procedures did not pose any threat to the lives of the patients.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	12 April 2012
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: 626
Worldwide total number of subjects	626
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)	75
Adults (18-64 years)	522
From 65 to 84 years	29
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants were recruited at 6 clinical sites in the US.

Pre-assignment

Screening details:

Of the 855 participants screened, 626 were randomized in the study. Of the 229 participants not randomized into the study, 151 did not meet the study criteria; 3 developed AEs; 10 were lost to follow-up; 4 violated protocol; 28 withdrew consent; and the remaining 33 were not randomized for other reasons.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Fluticasone Propionate Nasal Spray

Arm description:

Two sprays of Fluticasone propionate nasal spray (50 mcg/spray) per nostril to be administered in morning (Total dose 200 mcg).

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

Dosage and administration details:

50 mcg/spray (16 mL bottle – 120 metered sprays)

Arm title	Placebo Nasal Spray
------------------	---------------------

Arm description:

Two sprays of placebo per nostril to be administered in morning

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

Dosage and administration details:

50 mcg/spray (16 mL bottle – 120 metered sprays)

Number of subjects in period 1	Fluticasone Propionate Nasal Spray	Placebo Nasal Spray
Started	314	312
Completed	310	304
Not completed	4	8
Consent withdrawn by subject	1	3
Adverse event, non-fatal	-	2
Lost to follow-up	-	1
Could not attend appointment	1	1
Protocol deviation	2	1

Baseline characteristics

Reporting groups

Reporting group title	Fluticasone Propionate Nasal Spray
Reporting group description: Two sprays of Fluticasone propionate nasal spray (50 mcg/spray) per nostril to be administered in morning (Total dose 200 mcg).	
Reporting group title	Placebo Nasal Spray
Reporting group description: Two sprays of placebo per nostril to be administered in morning	

Reporting group values	Fluticasone Propionate Nasal Spray	Placebo Nasal Spray	Total
Number of subjects	314	312	626
Age categorical Units: Subjects			
In utero			0
Preterm newborn infants (gestational age < 37 wks)			0
Newborns (0-27 days)			0
Infants and toddlers (28 days-23 months)			0
Children (2-11 years)			0
Adolescents (12-17 years)			0
Adults (18-64 years)			0
From 65-84 years			0
85 years and over			0
Age continuous Units: years			
arithmetic mean	40.4	40.5	
standard deviation	± 14.55	± 16.36	-
Gender categorical Units: Subjects			
Female	212	201	413
Male	102	111	213
Race Units: Subjects			
American Indian or Alaska Native	1	0	1
Asian	1	2	3
Black or African American	36	38	74
White	272	270	542
Native Hawaiian or other Pacific Islander	1	1	2
Multiple	3	1	4

End points

End points reporting groups

Reporting group title	Fluticasone Propionate Nasal Spray
Reporting group description: Two sprays of Fluticasone propionate nasal spray (50 mcg/spray) per nostril to be administered in morning (Total dose 200 mcg).	
Reporting group title	Placebo Nasal Spray
Reporting group description: Two sprays of placebo per nostril to be administered in morning	

Primary: Mean Change From Baseline in Reflective Total Ocular Symptom Score (rTOSS)

End point title	Mean Change From Baseline in Reflective Total Ocular Symptom Score (rTOSS)
End point description: The Reflective Total Ocular Symptom Score (rTOSS) is the sum of 3 individual participant-assessed symptom scores (eye itching/burning, eye tearing/watering, and eye redness), each evaluated using a scale of 0=None, 1=Mild, 2=Moderate, or 3=Severe, for a possible score of 0-9. Subjects completed rTOSS in the evening (PM rTOSS; 12 hours post morning nasal spray use) and once in the morning (AM score: prior to nasal spray use). Daily (i.e. during one dosing interval) rTOSS is defined as the average of the PM rTOSS and the AM rTOSS of the next day prior to AM dosing. The mean change from baseline in (daily, AM, PM) TOSS was calculated as the subject's treatment period mean (over 14 days; from Day 0 PM to Day 14 AM) minus the baseline period (placebo run-in) mean.	
End point type	Primary
End point timeframe: Baseline to 14 days	

End point values	Fluticasone Propionate Nasal Spray	Placebo Nasal Spray		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	314	312		
Units: Score on Scale				
arithmetic mean (standard deviation)	-0.91 (± 1.625)	-0.63 (± 1.525)		

Statistical analyses

Statistical analysis title	Reflective Total Ocular Symptom Score (rTOSS)
Comparison groups	Placebo Nasal Spray v Fluticasone Propionate Nasal Spray

Number of subjects included in analysis	626
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.0024
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	-0.36
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.59
upper limit	-0.13

Secondary: Mean Change From Baseline in AM rTOSS

End point title	Mean Change From Baseline in AM rTOSS
End point description:	
rTOSS is the sum of 3 individual participant-assessed symptom scores (eye itching/ burning, eye tearing/watering, and eye redness), each evaluated using a scale of 0=None, 1=Mild, 2=Moderate, or 3=Severe, for a possible score of 0-9. For AM rTOSS, subject	
End point type	Secondary
End point timeframe:	
Baseline to 14 days	

End point values	Fluticasone Propionate Nasal Spray	Placebo Nasal Spray		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	314	312		
Units: Score on scale				
arithmetic mean (standard deviation)	-0.96 (± 1.627)	-0.68 (± 1.573)		

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change From Baseline in PM rTOSS

End point title	Mean Change From Baseline in PM rTOSS
End point description:	
rTOSS is the sum of 3 individual participant-assessed symptom scores (eye itching/ burning, eye tearing/watering, and eye redness), each evaluated using a scale of 0=None, 1=Mild, 2=Moderate, or 3=Severe, for a possible score of 0-9. For PM rTOSS, subjects completed rTOSS in the evening, 12 hours post morning nasal spray use. The mean change from baseline in PM rTOSS was calculated as the subject's treatment period mean (over 14 days) minus the baseline period (placebo run-in) mean.	
End point type	Secondary

End point timeframe:

Baseline to 14 days

End point values	Fluticasone Propionate Nasal Spray	Placebo Nasal Spray		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	314	312		
Units: Score on scale				
arithmetic mean (standard deviation)	-0.87 (\pm 1.735)	-0.6 (\pm 1.577)		

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change From Baseline in Individual AM Reflective Ocular Symptom Scores for Eye Itching/Burning

End point title	Mean Change From Baseline in Individual AM Reflective Ocular Symptom Scores for Eye Itching/Burning
-----------------	---

End point description:

The AM Reflective Ocular Symptom Score was assessed individually for eye itching/burning using a scale of 0=None, 1=Mild, 2=Moderate, or 3=Severe, for a possible score of 0-9. For evaluation, subjects completed the scoring in the morning, prior to nasal spray use. The mean change from baseline in AM Reflective Ocular Symptom Score (eye itching and burning) was calculated as the subject's treatment period mean (over 14 days) minus the baseline period (placebo run-in) mean

End point type	Secondary
----------------	-----------

End point timeframe:

Baseline to 14 days

End point values	Fluticasone Propionate Nasal Spray	Placebo Nasal Spray		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	314	312		
Units: Score on scale				
arithmetic mean (standard deviation)	-0.35 (\pm 0.581)	-0.28 (\pm 0.553)		

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change From Baseline in Individual PM Reflective Ocular Symptom Scores for Eye Itching/Burning

End point title	Mean Change From Baseline in Individual PM Reflective Ocular Symptom Scores for Eye Itching/Burning
End point description:	
The PM Reflective Ocular Symptom Score was assessed individually for eye itching/burning using a scale of 0=None, 1=Mild, 2=Moderate, or 3=Severe, for a possible score of 0-9. For evaluation, subjects completed the scoring in the evening, 12 hours post morning nasal spray use. The mean change from baseline in PM Reflective Ocular Symptom Score (eye itching and burning) was calculated as the subject's treatment period mean (over 14 days) minus the baseline period (placebo run-in) mean	
End point type	Secondary
End point timeframe:	
Baseline to 14 days	

End point values	Fluticasone Propionate Nasal Spray	Placebo Nasal Spray		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	314	312		
Units: Score on scale				
arithmetic mean (standard deviation)	-0.33 (± 0.626)	-0.24 (± 0.554)		

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change From Baseline in Individual AM Reflective Ocular Symptom Scores for Eye Tearing/Watering

End point title	Mean Change From Baseline in Individual AM Reflective Ocular Symptom Scores for Eye Tearing/Watering
End point description:	
The AM Reflective Ocular Symptom Score was assessed individually for eye tearing/watering using a scale of 0=None, 1=Mild, 2=Moderate, or 3=Severe, for a possible score of 0-9. For evaluation, subjects completed the scoring in the morning, prior to nasal spray use. The mean change from baseline in AM Reflective Ocular Symptom Score (eye tearing/watering) was calculated as the subject's treatment period mean (over 14 days) minus the baseline period (placebo run-in) mean.	
End point type	Secondary
End point timeframe:	
Baseline to 14 days	

End point values	Fluticasone Propionate Nasal Spray	Placebo Nasal Spray		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	314	312		
Units: Score on scale				
arithmetic mean (standard deviation)	-0.35 (± 0.596)	-0.24 (± 0.589)		

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change From Baseline in Individual PM Reflective Ocular Symptom Scores for Eye Tearing/Watering

End point title	Mean Change From Baseline in Individual PM Reflective Ocular Symptom Scores for Eye Tearing/Watering
-----------------	--

End point description:

The PM Reflective Ocular Symptom Score was assessed individually for eye tearing/watering using a scale of 0=None, 1=Mild, 2=Moderate, or 3=Severe, for a possible score of 0-9. For evaluation, subjects completed the scoring in the evening, 12 hours post morning nasal spray use. The mean change from baseline in PM Reflective Ocular Symptom Score (eye tearing/watering) was calculated as the subject's treatment period mean (over 14 days) minus the baseline period (placebo run-in) mean.

End point type	Secondary
----------------	-----------

End point timeframe:

Baseline to 14 days

End point values	Fluticasone Propionate Nasal Spray	Placebo Nasal Spray		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	314	312		
Units: Score on scale				
arithmetic mean (standard deviation)	-0.32 (\pm 0.653)	-0.19 (\pm 0.586)		

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change From Baseline in Individual AM Reflective Ocular Symptom Scores for Eye Redness

End point title	Mean Change From Baseline in Individual AM Reflective Ocular Symptom Scores for Eye Redness
-----------------	---

End point description:

The AM Reflective Ocular Symptom Score was assessed individually for eye redness using a scale of 0=None, 1=Mild, 2=Moderate, or 3=Severe, for a possible score of 0-9. For evaluation, subjects completed the scoring in the morning, prior to nasal spray use. The mean change from baseline in AM Reflective Ocular Symptom Score (eye redness) was calculated as the subject's treatment period mean (over 14 days) minus the baseline period (placebo run-in) mean

End point type	Secondary
----------------	-----------

End point timeframe:

Baseline to 14 days

End point values	Fluticasone Propionate Nasal Spray	Placebo Nasal Spray		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	314	312		
Units: Score on scale				
arithmetic mean (standard deviation)	-0.26 (± 0.597)	-0.17 (± 0.613)		

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change From Baseline in Individual PM Reflective Ocular Symptom Scores for Eye Redness

End point title	Mean Change From Baseline in Individual PM Reflective Ocular Symptom Scores for Eye Redness
-----------------	---

End point description:

The PM Reflective Ocular Symptom Score was assessed individually for eye redness using a scale of 0=None, 1=Mild, 2=Moderate, or 3=Severe, for a possible score of 0-9. For evaluation, subjects completed the scoring in the evening, 12 hours post morning nasal spray use. The mean change from baseline in PM Reflective Ocular Symptom Score (eye redness) was calculated as the subject's treatment period mean (over 14 days) minus the baseline period (placebo run-in) mean.

End point type	Secondary
----------------	-----------

End point timeframe:

Baseline to 14 days

End point values	Fluticasone Propionate Nasal Spray	Placebo Nasal Spray		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	314	312		
Units: Score on scale				
arithmetic mean (standard deviation)	-0.22 (± 0.628)	-0.17 (± 0.635)		

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change From Baseline in AM Pre-dose Instantaneous Total Ocular Symptom Scores (iTOSS)

End point title	Mean Change From Baseline in AM Pre-dose Instantaneous Total Ocular Symptom Scores (iTOSS)
-----------------	--

End point description:

Instantaneous total ocular symptom scores (iTOSS) assessments are self perceived evaluation of symptom severity immediately before the dose (how the subject feels at that point in time). iTOSS (possible score of 0-9) is the sum of 3 individual participant-assessed symptom scores for eye itching/burning, eye tearing/watering, and eye redness each evaluated using a scale of 0=None, 1=Mild, 2=Moderate, or 3=Severe. Mean changes from baseline were calculated as treatment period iTOSS minus baseline iTOSS.

End point type	Secondary
----------------	-----------

End point timeframe:

Baseline to 14 days

End point values	Fluticasone Propionate Nasal Spray	Placebo Nasal Spray		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	314	312		
Units: Score on a scale				
arithmetic mean (standard deviation)	-0.8 (± 1.443)	-0.55 (± 1.531)		

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change From Baseline in Reflective Nasal Congestion Symptom Score (rNCSS)

End point title	Mean Change From Baseline in Reflective Nasal Congestion Symptom Score (rNCSS)
-----------------	--

End point description:

The rNCSS is a participant perceived evaluation of overall congestion symptom severity (evaluated using a scale of 0=None, 1=Mild, 2=Moderate, or 3=Severe) which was completed once in the evening (PM), and once in the morning (AM). rNCSS is defined as the average of the PM rNCSS and the AM rNCSS of the next day prior to AM dosing. The mean change from baseline in rNCSS (daily, AM, PM) was calculated as the subject's treatment period mean (over 14 days; from Day 0 PM to Day 14 AM) minus the baseline period (placebo run-in) mean.

End point type	Secondary
----------------	-----------

End point timeframe:

Baseline to 14 days

End point values	Fluticasone Propionate Nasal Spray	Placebo Nasal Spray		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	314	312		
Units: Score on scale				
arithmetic mean (standard deviation)	-0.34 (± 0.547)	-0.2 (± 0.443)		

Statistical analyses

No statistical analyses for this end point

Secondary: End-of-treatment Assessment of Response to Therapy for Ocular Symptoms

End point title	End-of-treatment Assessment of Response to Therapy for Ocular Symptoms
End point description: Overall response to therapy assessment was done using a 7-point categorical scale in which participants rated their response to therapy as follows: +3 = Significantly Improved; +2 = Moderately Improved; +1 = Mildly Improved; 0 = No Change; -1 = Mildly Worse; -2 = Moderately Worse; -3 = Significantly Worse.	
End point type	Secondary
End point timeframe: Baseline to 14 days	

End point values	Fluticasone Propionate Nasal Spray	Placebo Nasal Spray		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	313	309		
Units: Participants				
number (not applicable)				
Significantly improved	22	16		
Moderately improved	76	59		
Mildly improved	79	71		
No change	81	97		
Mildly Worse	21	20		
Moderately Worse	24	24		
Significantly Worse	10	22		

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change in Objective Assessment of Conjunctival Redness

End point title	Mean Change in Objective Assessment of Conjunctival Redness
End point description: Conjunctival redness was evaluated as a clinical sign of SAR by the investigator. Scoring of severity was rated according to a 4-point scale: 0 = normal; 1 = Slightly pink; 2 = Moderately pink, some dilation; 3 = Intense red vessels, dilated.	

End point type	Secondary
End point timeframe:	
Baseline to 14 days	

End point values	Fluticasone Propionate Nasal Spray	Placebo Nasal Spray		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	314	312		
Units: Score on scale				
arithmetic mean (standard deviation)	-0.2 (± 0.815)	-0.15 (± 0.736)		

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Changes From Baseline in Mini Rhinoconjunctivitis Quality of Life Questionnaire (MiniRQLQ) Scores

End point title	Mean Changes From Baseline in Mini Rhinoconjunctivitis Quality of Life Questionnaire (MiniRQLQ) Scores
-----------------	--

End point description:

MiniRQLQ is a 14-item, disease-specific instrument for assessing the impact of allergic rhinitis on activities of daily living and overall well-being. It measures five domains of functional impairment that are most important to subjects with SAR: practical problems, nasal symptoms, eye symptoms, activity limitations, and other symptoms. Participants scored their degree of impairment on a seven-point scale. (0 - 6). Mini RQLQ final score is the average of sub-scales, ranges from 0 (best possible outcome) to 6 (worst possible outcome).

End point type	Secondary
End point timeframe:	
Baseline to 14 days	

End point values	Fluticasone Propionate Nasal Spray	Placebo Nasal Spray		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	314	311		
Units: Score on scale				
arithmetic mean (standard deviation)	-0.98 (± 1.311)	-0.49 (± 1.091)		

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Changes From Baseline in Individual MiniRQLQ Scores: Domain - Activities

End point title	Mean Changes From Baseline in Individual MiniRQLQ Scores: Domain - Activities
-----------------	---

End point description:

MiniRQLQ is a 14-item, disease-specific instrument for assessing the impact of allergic rhinitis on activities of daily living and overall well-being. Activity limitations is one of the domains of Mini RQLQ scores. Participants scored their degree of impairment on a seven-point scale (0 = not troubled, 6 = extremely troubled).

End point type	Secondary
----------------	-----------

End point timeframe:

Baseline to 14 days

End point values	Fluticasone Propionate Nasal Spray	Placebo Nasal Spray		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	314	311		
Units: Score on scale				
arithmetic mean (standard deviation)	-0.93 (\pm 1.384)	-0.39 (\pm 1.269)		

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Changes From Baseline in Individual MiniRQLQ Scores: Domain - Practical Problems

End point title	Mean Changes From Baseline in Individual MiniRQLQ Scores: Domain - Practical Problems
-----------------	---

End point description:

MiniRQLQ is a 14-item, disease-specific instrument for assessing the impact of allergic rhinitis on activities of daily living and overall well-being. Activity limitations is one of the domains of Mini RQLQ scores. Participants scored their degree of impairment on a seven-point scale (0 = not troubled, 6 = extremely troubled).

End point type	Secondary
----------------	-----------

End point timeframe:

Baseline to 14 days

End point values	Fluticasone Propionate Nasal Spray	Placebo Nasal Spray		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	314	311		
Units: Score on a scale				
arithmetic mean (standard deviation)	-1.04 (\pm 1.476)	-0.57 (\pm 1.258)		

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Changes From Baseline in Individual MiniRQLQ Scores: Domain - Nose Symptoms

End point title	Mean Changes From Baseline in Individual MiniRQLQ Scores: Domain - Nose Symptoms
-----------------	--

End point description:

MiniRQLQ is a 14-item, disease-specific instrument for assessing the impact of allergic rhinitis on activities of daily living and overall well-being. "Nose Symptoms" is one of the domains of Mini RQLQ scores. Participants scored their degree of impairment on a seven-point scale (0 = not troubled, 6 = extremely troubled).

End point type	Secondary
----------------	-----------

End point timeframe:

Baseline to 14 days

End point values	Fluticasone Propionate Nasal Spray	Placebo Nasal Spray		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	313	310		
Units: Score on scale				
arithmetic mean (standard deviation)	-1.09 (\pm 1.456)	-0.5 (\pm 1.257)		

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Changes From Baseline in Individual MiniRQLQ Scores: Domain - Eye Symptoms

End point title	Mean Changes From Baseline in Individual MiniRQLQ Scores: Domain - Eye Symptoms
-----------------	---

End point description:

MiniRQLQ is a 14-item, disease-specific instrument for assessing the impact of allergic rhinitis on activities of daily living and overall well-being. "Eye Symptoms" is one of the domains of Mini RQLQ scores. Participants scored their degree of impairment on a seven-point scale (0 = not troubled, 6 = extremely troubled).

End point type	Secondary
----------------	-----------

End point timeframe:

Baseline to 14 days

End point values	Fluticasone Propionate Nasal Spray	Placebo Nasal Spray		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	313	310		
Units: Score on a scale				
arithmetic mean (standard deviation)	-0.98 (± 1.512)	-0.55 (± 1.284)		

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Changes From Baseline in Individual MiniRQLQ Scores: Domain - Other Symptoms

End point title	Mean Changes From Baseline in Individual MiniRQLQ Scores: Domain - Other Symptoms
-----------------	---

End point description:

MiniRQLQ is a 14-item, disease-specific instrument for assessing the impact of allergic rhinitis on activities of daily living and overall well-being. "Other Symptoms" is one of the domains of Mini RQLQ scores. Participants scored their degree of impairment on a seven-point scale (0 = not troubled, 6 = extremely troubled).

End point type	Secondary
----------------	-----------

End point timeframe:

Baseline to 14 days

End point values	Fluticasone Propionate Nasal Spray	Placebo Nasal Spray		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	313	310		
Units: Score on a scale				
arithmetic mean (standard deviation)	-0.89 (± 1.607)	-0.48 (± 1.294)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Participants were followed for the duration of study, an average of 3 weeks

Assessment type	Systematic
-----------------	------------

Dictionary used

Dictionary name	MedDRA
-----------------	--------

Dictionary version	15.1
--------------------	------

Reporting groups

Reporting group title	Fluticasone Propionate Nasal Spray
-----------------------	------------------------------------

Reporting group description:

Two sprays of Fluticasone propionate nasal spray (50 mcg/spray) per nostril to be administered in morning (Total dose 200 mcg).

Reporting group title	Placebo Nasal Spray
-----------------------	---------------------

Reporting group description:

Two sprays of placebo per nostril to be administered in morning.

Serious adverse events	Fluticasone Propionate Nasal Spray	Placebo Nasal Spray	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 314 (0.00%)	0 / 312 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	

Frequency threshold for reporting non-serious adverse events: 0.3 %

Non-serious adverse events	Fluticasone Propionate Nasal Spray	Placebo Nasal Spray	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	8 / 314 (2.55%)	8 / 312 (2.56%)	
Injury, poisoning and procedural complications			
Laceration			
subjects affected / exposed	1 / 314 (0.32%)	0 / 312 (0.00%)	
occurrences (all)	1	0	
Vascular disorders			
Hypertension			
subjects affected / exposed	1 / 314 (0.32%)	0 / 312 (0.00%)	
occurrences (all)	1	0	

Cardiac disorders			
Palpitations			
subjects affected / exposed	1 / 314 (0.32%)	0 / 312 (0.00%)	
occurrences (all)	1	0	
Nervous system disorders			
Headache			
subjects affected / exposed	2 / 314 (0.64%)	0 / 312 (0.00%)	
occurrences (all)	2	0	
Migraine			
subjects affected / exposed	0 / 314 (0.00%)	1 / 312 (0.32%)	
occurrences (all)	0	1	
General disorders and administration site conditions			
Pain			
subjects affected / exposed	0 / 314 (0.00%)	1 / 312 (0.32%)	
occurrences (all)	0	1	
Pyrexia			
subjects affected / exposed	1 / 314 (0.32%)	2 / 312 (0.64%)	
occurrences (all)	1	2	
Thirst			
subjects affected / exposed	1 / 314 (0.32%)	0 / 312 (0.00%)	
occurrences (all)	1	0	
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 314 (0.00%)	1 / 312 (0.32%)	
occurrences (all)	0	1	
Respiratory, thoracic and mediastinal disorders			
Epistaxis			
subjects affected / exposed	0 / 314 (0.00%)	1 / 312 (0.32%)	
occurrences (all)	0	1	
Respiratory Tract Congestion			
subjects affected / exposed	0 / 314 (0.00%)	1 / 312 (0.32%)	
occurrences (all)	0	1	
Throat irritation			
subjects affected / exposed	1 / 314 (0.32%)	0 / 312 (0.00%)	
occurrences (all)	1	0	
Skin and subcutaneous tissue disorders			

Dermatitis subjects affected / exposed occurrences (all)	0 / 314 (0.00%) 0	1 / 312 (0.32%) 1	
Infections and infestations			
Bronchitis subjects affected / exposed occurrences (all)	0 / 314 (0.00%) 0	2 / 312 (0.64%) 2	
Gastrointestinal Viral subjects affected / exposed occurrences (all)	1 / 314 (0.32%) 1	0 / 312 (0.00%) 0	
Influenza subjects affected / exposed occurrences (all)	0 / 314 (0.00%) 0	1 / 312 (0.32%) 1	

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