ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: 08/21/2014

ClinicalTrials.gov ID: NCT00609674

Study Identification

Unique Protocol ID:	FFU111439
Brief Title:	A Clinical Study To Test A Nasal Spray (Fluticasone Furoate Nasal Spray) For The Treatment Of Perennial (Year-round) Allergic Rhinitis
Official Title:	A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Multicenter Study to Evaluate the Efficacy and Safety of Once-Daily Intranasal Administration of Fluticasone Furoate Nasal Spray 110mcg in Adult and Adolescent Subjects 12 Years of Age and Older With Perennial Allergic Rhinitis (PAR)
Secondary IDs:	

Study Status

Record Verification:	February 2011
Overall Status:	Completed
Study Start:	January 2008
Primary Completion:	June 2008 [Actual]
Study Completion:	June 2008 [Actual]

Sponsor/Collaborators

Sponsor:	GlaxoSmithKline
Responsible Party:	Sponsor
Collaborators:	

Oversight

FDA Regulated?:	Yes
Applicable Trial?:	Section 801 Clinical Trial? Yes Delayed Posting? No
IND/IDE Protocol?:	Yes
IND/IDE Information:	Grantor: CDER IND/IDE Number: 48,647 Serial Number: Has Expanded Access? No
Review Board:	Approval Status: Approved Board Name: Copernicus IRB Board Affiliation: Phone: 1-888-303-2224 Email: rsipes@cgirb.com
Data Monitoring?:	
Plan to Share Data?:	
Oversight Authorities:	United States: Food and Drug Administration

Study Description

Brief Summary:	The purpose of this study is to compare the effects (effectiveness and safety) of an intranasal corticosteroid (fluticasone furoate nasal spray [FFNS]), with a placebo nasal spray for the treatment of perennial (year-round) allergic rhinitis.
Detailed Description:	

Conditions

Conditions:	Rhinitis, Allergic, Perennial
Keywords:	Perennial allergic rhinitis; fluticasone furoate nasal spray

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 4

Intervention Model:	Parallel Assignment
Number of Arms:	2
Masking:	Double Blind (Subject, Investigator)
Allocation:	Randomized
Endpoint Classification:	Safety/Efficacy Study
Enrollment:	315 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: fluticasone furoate nasal spray	Drug: Fluticasone furoate nasal spray Fluticasone furoate nasal spray Other Names: • Fluticasone furoate nasal spray
Placebo Comparator: Placebo	Drug: Placebo Placebo

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age:	12 Years
Maximum Age:	
Gender:	Both
Accepts Healthy Volunteers?:	No
Criteria:	Inclusion Criteria:

Subjects eligible for enrollment in the study must meet all of the following criteria:

- Informed consent
- Subject has provided an appropriately signed and dated informed consent.
- An appropriately signed and dated assent must be obtained from the parents or guardian if the subject is a child under 18 years of age.
- Outpatient
- Subject is treatable on an outpatient basis.
- Age

- ≥ 12 years at Visit 2
- ≥ 18 years at Visit 1 for Russia and Germany
- Male or eligible female. Female subjects should not be enrolled if they plan to become pregnant during the time of study participation. A urine pregnancy test will be performed for all females of childbearing potential at Visits 1, 2, 5, and Visit 6/ Early Withdrawal to determine if the subject is pregnant.

To be eligible for entry into the study, females of childbearing potential must commit to the consistent and correct use of an acceptable method of birth control, as defined by the following:

- Abstinence Females of childbearing potential who are not sexually active must commit to complete abstinence from intercourse for two weeks before exposure to the study drug, throughout the clinical trial, and for a period after the trial to account for elimination of the drug (minimum of six days).
- Oral contraceptive (either combined estrogen/progestin or progestin only),
- Injectable progestogen,
- Implants of levonorgestrel,
- Percutaneous contraceptive patches,
- Intrauterine device (IUD) or intrauterine system (IUS) with a documented failure rate of less than 1% per year,
- Male partner who is sterile (vasectomy with documentation of azospermia) prior to the female subject's entry into the study and is the sole sexual partner for that female subject,
- Double barrier method-condom or occlusive cap (diaphragm or cervical /vault caps) plus spermicide,
- Estrogenic vaginal ring
- Diagnosis of PAR to include:
- A positive skin test (by prick method) response to appropriate perennial allergen (house dust mites, animal dander, mold, or cockroach) within last 12 months prior to Visit 1 or at Visit 1.

A positive skin test is defined as a wheal ≥3mm larger than the diluent control for prick testing.

- Two year medical history and past treatment of PAR (written or verbal confirmation) which includes perennial, i.e., year-round, symptoms. PAR symptoms would include nasal congestion, rhinorrhea, nasal itching and sneezing, eye itching/ burning, eye tearing/watering, and eye redness.

In vitro tests for specific IgE (such as RAST, PRIST) will not be allowed for the diagnosis of PAR.

NOTE: Subjects who meet the above criteria for PAR and who also have a history of allergy to a seasonal pollen that will be present in their geographic area during study participation are NOT eligible for randomization.

- Environment
- Subject must be symptomatic to appropriate perennial allergen (animal dander, house dust mites, cockroach, mold) and willing to maintain same environment throughout the study.
- Ability to comply with study procedures
- Subject understands and is willing, able and likely to comply with study procedures and restrictions.
- Literate
- Subject must be able to read, comprehend, and record information in English or native language.

Randomization Criteria

At Visit 2, the subject must meet the following criteria:

- Average of the last 8 rTNSS assessments (4 AM assessments, 4 PM assessments) over the four 24-hours periods prior to randomization must be ≥6. This includes the AM assessment on the morning of the randomization visit.
- Average of the last 8 reflective nasal symptom assessments for congestion (4 AM assessments, 4 PM assessments) over the four 24-hour periods prior to randomization must be ≥2. This includes the AM assessment on the morning of the randomization visit.
- Average of the last eight rTOSS assessments (4 AM assessments, 4 PM assessments) over the four 24-hour periods prior to randomization must be ≥ 4. This includes the AM assessment on the morning of the randomization visit.
- The subject has demonstrated the ability to comply with the use of the daily e-diary, defined as completion of at least 80% of the assessments during the screening period.

Exclusion Criteria:

Subjects meeting any of the following criteria must not be enrolled in the study:

- Significant concomitant medical conditions, defined as but not limited to:
- a historical or current evidence of clinically significant uncontrolled disease of any body system (e.g., tuberculosis, psychological disorders, eczema). Significant is defined as any disease that, in the opinion of the investigator, would put the safety of the subject at risk through study participation or which would confound the interpretation of the study results if the disease/condition exacerbated during the study.
- a severe physical obstruction of the nose (e.g., deviated septum or nasal polyp) or nasal septal perforation that could affect the deposition of double blind intranasal study drug
- nasal (e.g., nasal septum) or ocular injury/surgery in the last 3 months
- asthma, with the exception of mild intermittent asthma [NAEPP, 2007; GINA, 2006], or very mild asthma (Canada) [Lemiére, 2004].

NOTE: Subjects will be allowed to use short-acting inhaled beta2 agonists ONLY on an as needed basis.

- rhinitis medicamentosa
- bacterial or viral infection (e.g., common cold) of the eyes or upper respiratory tract within two weeks of Visit 1 or during the screening period
- documented evidence of acute or significant chronic sinusitis, as determined by the individual investigator
- current or history of glaucoma and/or ocular herpes simplex
- current cataract
- physical impairment that would affect subject's ability to participate safely and fully in the study
- clinical evidence of a Candida infection of the nose
- history of psychiatric disease, intellectual deficiency, poor motivation, substance abuse (including drug and alcohol) or other conditions that will limit the validity of informed consent or that would confound the interpretation of the study results
- history of adrenal insufficiency
- Use of corticosteroids, defined as:
- Intranasal corticosteroid within 4 weeks prior to Visit 1 (e.g., FLONASE™, VERAMYST, Nasonex, Rhinocort).
- Inhaled, oral, intramuscular, intravenous, ocular, and/or dermatological corticosteroid (with the exception of hydrocortisone cream/ointment, 1% or less, or equivalent) within 8 weeks prior to Visit 1.
- Use of other allergy medications within the timeframe indicated relative to Visit 1
- Intranasal or ocular cromolyn within 14 days prior to Visit 1 (e.g., Nasalcrom, Crolom)
- Short-acting prescription and non-prescription antihistamines, including ocular preparations and antihistamines contained in insomnia and "night time" pain formulations, within 3 days prior to Visit 1 (e.g., Benadryl, Chlortrimeton, Dimetane, Tavist)

- Long-acting antihistamines within 10 days prior to Visit 1, including loratadine, desloratadine, fexofenadine, cetirizine, levocetirizine, terfenadine (e.g., Allegra, Claritin, Clarinex, Zyrtec)
- Long-acting antihistamine, astemizole, within 12 weeks prior to Visit 1
- Intranasal antihistamines (e.g., Astelin) within 2 weeks prior to Visit 1
- Oral or intranasal decongestants within 3 days prior to Visit 1 (e.g., Sudafed)
- Long-acting beta-agonists within 3 days prior to Visit 1 (e.g., SEREVENT™, Foradil)
- Intranasal, oral, or inhaled anticholinergics within 3 days prior to Visit 1 (e.g., Atrovent)
- Histamine H2-receptor antagonists including cimetidine, ranitidine, famotidine, nizatidine (e.g., ZANTAC™, Tagamet, Pepcid, Axid) within 1 day prior to Visit 1
- Oral antileukotrienes within 3 days of Visit 1 (e.g., Singulair)
- Subcutaneous omalizumab (Xolair) within 5 months of Visit 1
- Subjects are not permitted to use any artificial tears, eyewashes/nasal irrigation solutions, homeopathic preparations, lubricants, sympathomimetic or vasoconstrictor preparations during the screening and treatment periods. No exclusion period prior to screening (Visit 1) is required for these treatments.
- Use of other medications that may affect allergic rhinitis or its symptoms
- Chronic use of concomitant medications, such as tricyclic antidepressants, that would affect assessment of the effectiveness of the study drug
- Use of other intranasally administered medications (e.g., Miacalcin)
- Use of immunosuppressive medications eight weeks prior to screening and during the study
- Immunotherapy Immunotherapy patients may be enrolled in the study as long as the immunotherapy was not initiated within 30 days of Visit 1 and if the dose has remained fixed over the 30 days prior to Visit 1, and the dose will remain fixed for the duration of the study.
- Use of any medications that significantly alter the pharmacokinetics of fluticasone furoate, including ritonavir and ketoconazole
- Allergy/Intolerance
- Known hypersensitivity to corticosteroids, or any excipients in the product
- Use of contact lenses
- Use of Nasal Continuous Positive Airway Pressure (C-PAP) device (mask or pillow)
- Clinical trial/experimental medication experience
- Participation in a clinical trial within 12 months prior to Visit 1
- Participation in a previous or current FFNS (GW685698X) clinical study
- Positive pregnancy test or female who is breastfeeding
- Has a positive or inconclusive pregnancy test at Visit 1 or Visit 2
- Affiliation with investigational site
- Subject is a participating investigator, sub-investigator, study co-ordinator, or employee of a participating investigator, or is an immediate family member of the aforementioned.
- Current tobacco use
- Subject currently uses, or has used within the past year, smoking products including cigarettes, cigars, and pipe or chewing tobacco.
- Chickenpox or measles
- A subject is not eligible if he/she currently has chickenpox or measles, or has been exposed to chickenpox or measles during the last three weeks and is non-immune. If a subject develops chickenpox or measles during the study, he/she will be withdrawn from the study. If a non-immune subject is exposed to chickenpox or measles during the study, his/her continuation in the study will be at the discretion of the investigator, taking into consideration the likelihood of developing active disease.

- Findings of a clinically significant, abnormal electrocardiogram (ECG)
- Findings of a clinically significant laboratory abnormality

Contacts/Locations

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References

Citations: Given JT, Cheema AS,Dreykluft T, Stillerman A, Silvey MJ, Wu W, Snowise NG; Philpot E . Fluticasone Furoate Nasal Spray Is Effective and Well Tolerated for Perennial Allergic Rhinitis in Adolescents and Adults . Am J Rhinol Allergy. 2010;24(6):444.

Links:

Study Data/Documents:

Study Results

Participant Flow

Reporting Groups

	Description
Placebo	Placebo nasal spray
Fluticasone Furoate 110 mcg	Once-daily fluticasone furoate (FF) nasal spray 110 mcg

Overall Study

	Placebo	Fluticasone Furoate 110 mcg
Started	155	160
Completed	148	153
Not Completed	7	7
Adverse Event	1	1
Protocol Violation	3	5
Lost to Follow-up	1	0
Withdrew consent	2	1

Baseline Characteristics

Reporting Groups

	Description
Placebo	Placebo nasal spray
Fluticasone Furoate 110 mcg	Once-daily fluticasone furoate (FF) nasal spray 110 mcg

Baseline Measures

	Placebo	Fluticasone Furoate 110 mcg	Total
Number of Participants	155	160	315
Age, Continuous [units: years] Mean (Standard Deviation)	39.3 (15.06)	38.1 (14.18)	38.7 (14.61)
Gender, Male/Female [units: participants]			
Female	45	57	102
Male	110	103	213
Race/Ethnicity, Customized [units: participants]			
White	140	149	289
African American/African Heritage	11	3	14

	Placebo	Fluticasone Furoate 110 mcg	Total
American Indian/Alaska Native	0	2	2
Asian	4	3	7
Native Hawaiian/Other Pacific Islander	0	1	1
African American/African Heritage & Asian & White	0	1	1
Asian & White	0	1	1

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Mean Change From Baseline Over the Entire Treatment Period in Daily Reflective Total Nasal Symptom Scores (rTNSS)
Measure Description	TNSS is the sum of symptom scores for rhinorrhea, nasal congestion, nasal itching, and sneezing (each scored on a scale of 0 [none] to 3 [severe]; total possible score of 0 to 12). The rTNSS (performed in the morning [AM] and evening [PM]) was a rating of the severity of symptoms over the previous 12 hours. The daily rTNSS was the average of the AM rTNSS and PM rTNSS assessments. Change from baseline is calculated as the score at the end of study minus the score at baseline.
Time Frame	Daily; Baseline through End of Study (Week 4)
Safety Issue?	No

Analysis Population Description

Intent-to-Treat (ITT) Population: all randomized subjects who received at least one dose of study drug

Reporting Groups

	Description
Placebo	Placebo nasal spray
Fluticasone Furoate 110 mcg	Once-daily fluticasone furoate (FF) nasal spray 110 mcg

Measured Values

	Placebo	Fluticasone Furoate 110 mcg
Number of Participants Analyzed	155	160

	Placebo	Fluticasone Furoate 110 mcg
Mean Change From Baseline Over the Entire Treatment Period in Daily Reflective Total Nasal Symptom Scores (rTNSS) [units: Points on a scale] Least Squares Mean (Standard Error)	-2.45 (0.24)	-3.19 (0.23)

Statistical Analysis 1 for Mean Change From Baseline Over the Entire Treatment Period in Daily Reflective Total Nasal Symptom Scores (rTNSS)

Statistical Analysis Overview	Comparison Groups	Placebo, Fluticasone Furoate 110 mcg
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.004
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]

2. Secondary Outcome Measure:

Measure Title	Mean Change From Baseline Over the Entire Treatment Period in Morning (AM), Pre-dose Instantaneous Total Nasal Symptom Score (iTNSS)
Measure Description	The AM, pre-dose iTNSS is the sum of the 4 individual nasal symptom score assessments for rhinorrhea, nasal congestion, nasal itching, and sneezing performed at the moment immediately prior to taking the daily dose; each symptom is scored on a scale of 0 (none) to 3 (severe). Change from baseline is calculated as the score over the entire treatment period minus the score at baseline. TNSS: Total possible score ranges from 0 to 12.
Time Frame	Daily; Baseline through End of Study (Week 4)
Safety Issue?	No

Analysis Population Description

ITT Population

Reporting Groups

	Description
Placebo	Placebo nasal spray
Fluticasone Furoate 110 mcg	Once-daily fluticasone furoate (FF) nasal spray 110 mcg

Measured Values

	Placebo	Fluticasone Furoate 110 mcg
Number of Participants Analyzed	155	160
Mean Change From Baseline Over the Entire Treatment Period in Morning (AM), Pre-dose Instantaneous Total Nasal Symptom Score (iTNSS) [units: Points on a scale] Least Squares Mean (Standard Error)	-2.29 (0.25)	-2.97 (0.24)

3. Secondary Outcome Measure:

Measure Title	Mean Change From Baseline Over the Entire Treatment Period in Daily Reflective Total Ocular Symptom Scores (rTOSS)
Measure Description	The TOSS is equal to the sum of the three individual ocular symptom scores for eye itching/burning, eye tearing/ watering, and eye redness, where each symptom is scored on a scale of 0 (none) to 3 (severe); total possible score of 0 to 9. Change from baseline is calculated as the score at the end of study minus the score at baseline.
Time Frame	Daily; Baseline through End of Study (Week 4)
Safety Issue?	No

Analysis Population Description
ITT Population

Reporting Groups

	Description
Placebo	Placebo nasal spray
Fluticasone Furoate 110 mcg	Once-daily fluticasone furoate (FF) nasal spray 110 mcg

Measured Values

	Placebo	Fluticasone Furoate 110 mcg
Number of Participants Analyzed	155	160

	Placebo	Fluticasone Furoate 110 mcg
Mean Change From Baseline Over the Entire Treatment Period in Daily Reflective Total Ocular Symptom Scores (rTOSS) [units: Points on a scale] Least Squares Mean (Standard Error)	-1.99 (0.20)	-2.23 (0.19)

4. Secondary Outcome Measure:

Measure Title	Total Nasal Symptoms: Mean Change From Baseline Over the Entire Treatment Period in AM rTNSS
Measure Description	TNSS = the sum of symptom scores for rhinorrhea, nasal congestion, nasal itching, and sneezing (each scored on a scale of 0 [none] to 3 [severe]; total possible score of 0 to 12). The rTNSS (performed in the morning [AM] and evening [PM]) is a rating of the severity of symptoms over the previous 12 hours. Change from baseline is calculated as the score at the end of study minus the score at baseline.
Time Frame	Daily; Baseline through End of Study (Week 4)
Safety Issue?	No

Analysis Population Description

ITT Population

Reporting Groups

	Description
Placebo	Placebo nasal spray
Fluticasone Furoate 110 mcg	Once-daily fluticasone furoate (FF) nasal spray 110 mcg

Measured Values

	Placebo	Fluticasone Furoate 110 mcg
Number of Participants Analyzed	155	160
Total Nasal Symptoms: Mean Change From Baseline Over the Entire Treatment Period in AM rTNSS [units: Points on a scale] Least Squares Mean (Standard Error)	-2.40 (0.24)	-3.15 (0.23)

5. Secondary Outcome Measure:

Measure Title	Total Nasal Symptoms: Mean Change From Baseline Over the Entire Treatment Period in PM rTNSS
Measure Description	TNSS is the sum of symptom scores for rhinorrhea, nasal congestion, nasal itching, and sneezing (each scored on a scale of 0 [none] to 3 [severe]; total possible score of 0 to 12). The rTNSS (performed in the morning [AM] and evening [PM]) is a rating of the severity of symptoms over the previous 12 hours. Change from baseline is calculated as the score at the end of study minus the score at baseline.
Time Frame	Daily; Baseline through End of Study (Week 4)
Safety Issue?	No

Analysis Population Description
ITT Population

Reporting Groups

	Description
Placebo	Placebo nasal spray
Fluticasone Furoate 110 mcg	Once-daily fluticasone furoate (FF) nasal spray 110 mcg

Measured Values

	Placebo	Fluticasone Furoate 110 mcg
Number of Participants Analyzed	155	160
Total Nasal Symptoms: Mean Change From Baseline Over the Entire Treatment Period in PM rTNSS [units: Points on a scale] Least Squares Mean (Standard Error)	-2.51 (0.25)	-3.26 (0.24)

6. Secondary Outcome Measure:

Measure Title	Total Nasal Symptoms: Mean Percent Change From Baseline Over the Entire Treatment Period in Daily rTNSS and AM, Pre-dose iTNSS
Measure Description	The rTNSS is a rating of the severity of symptoms over the previous 12 hours and was performed in the AM (AM rTNSS) and PM (PM rTNSS). AM, pre-dose iTNSS: sum of the 4 individual nasal symptom score assessments for rhinorrhea, nasal congestion, nasal itching, and sneezing performed at the moment immediately prior to taking the daily dose. Each symptom is scored on a scale of 0 (none) to 3 (severe), with a total possible score range of 0 to 12. Change from baseline is calculated as the score at the end of study minus the score at baseline.
Time Frame	Daily; Baseline through End of Study (Week 4)
Safety Issue?	No

Analysis Population Description
ITT Population

Reporting Groups

	Description
Placebo	Placebo nasal spray
Fluticasone Furoate 110 mcg	Once-daily fluticasone furoate (FF) nasal spray 110 mcg

Measured Values

	Placebo	Fluticasone Furoate 110 mcg
Number of Participants Analyzed	155	160
Total Nasal Symptoms: Mean Percent Change From Baseline Over the Entire Treatment Period in Daily rTNSS and AM, Pre-dose iTNSS [units: percent change] Least Squares Mean (Standard Error)		
rTNSS	-26.39 (2.69)	-35.03 (2.59)
iTNSS	-24.87 (2.89)	-33.52 (2.77)

7. Secondary Outcome Measure:

Measure Title	Individual Nasal Symptoms: Mean Change From Baseline Over the Entire Treatment Period in Individual Daily Reflective Nasal Symptom Scores and AM, Pre-dose Instantaneous Nasal Symptom Scores for Rhinorrhea, Nasal Congestion, Nasal Itching, and Sneezing
Measure Description	The rTNSS is a rating of the severity of symptoms over the previous 12 hours and was performed in the AM (AM rTNSS) and PM (PM rTNSS). The AM, pre-dose iTNSS is the sum of the 4 individual nasal symptom score assessments for rhinorrhea, nasal congestion, nasal itching, and sneezing performed immediately prior to taking the daily dose. Change from baseline is calculated as the score at the end of study minus the score at baseline. Each symptom is scored on a scale of 0 (none) to 3 (severe), with a total possible score of 0 to 12.
Time Frame	Daily; Baseline through End of Study (Week 4)
Safety Issue?	No

Analysis Population Description
ITT Population

Reporting Groups

	Description
Placebo	Placebo nasal spray
Fluticasone Furoate 110 mcg	Once-daily fluticasone furoate (FF) nasal spray 110 mcg

Measured Values

	Placebo	Fluticasone Furoate 110 mcg
Number of Participants Analyzed	155	160
Individual Nasal Symptoms: Mean Change From Baseline Over the Entire Treatment Period in Individual Daily Reflective Nasal Symptom Scores and AM, Pre-dose Instantaneous Nasal Symptom Scores for Rhinorrhea, Nasal Congestion, Nasal Itching, and Sneezing [units: Points on a scale] Least Squares Mean (Standard Error)		
rTNSS - rhinorrhea	-0.57 (0.07)	-0.73 (0.06)
rTNSS - nasal congestion	-0.63 (0.06)	-0.80 (0.06)
rTNSS - nasal itching	-0.63 (0.07)	-0.82 (0.06)
rTNSS - sneezing	-0.63 (0.07)	-0.84 (0.06)
iTNSS - rhinorrhea	-0.52 (0.07)	-0.68 (0.07)
iTNSS - nasal congestion	-0.51 (0.06)	-0.71 (0.06)
iTNSS - nasal itching	-0.66 (0.07)	-0.81 (0.07)
iTNSS - sneezing	-0.60 (0.07)	-0.77 (0.07)

8. Secondary Outcome Measure:

Measure Title	Mean Change From Baseline Over the Entire Treatment Period in Both Individual AM Reflective and PM Reflective Nasal Symptom Scores for Rhinorrhea, Nasal Congestion, Nasal Itching, and Sneezing.
Measure Description	The rTNSS is a rating of the severity of symptoms over the previous 12 hours and was performed in the AM (AM rTNSS) and PM (PM rTNSS). Change from baseline is calculated as the score at the end of study minus the score at baseline. Each symptom is scored on a scale of 0 (none) to 3 (severe), with a total possible score of 0 to 12.
Time Frame	Daily; Baseline through End of Study (Week 4)

Safety Issue?	No

Analysis Population Description
ITT Population

Reporting Groups

	Description
Placebo	Placebo nasal spray
Fluticasone Furoate 110 mcg	Once-daily fluticasone furoate (FF) nasal spray 110 mcg

Measured Values

	Placebo	Fluticasone Furoate 110 mcg
Number of Participants Analyzed	155	160
Mean Change From Baseline Over the Entire Treatment Period in Both Individual AM Reflective and PM Reflective Nasal Symptom Scores for Rhinorrhea, Nasal Congestion, Nasal Itching, and Sneezing. [units: Points on a scale] Least Squares Mean (Standard Error)		
AM reflective - rhinorrhea	-0.58 (0.07)	-0.75 (0.06)
AM reflective - nasal congestion	-0.61 (0.06)	-0.80 (0.06)
AM reflective - nasal itching	-0.62 (0.07)	-0.80 (0.06)
AM reflective - sneezing	-0.61 (0.07)	-0.81 (0.06)
PM reflective - rhinorrhea	-0.57 (0.07)	-0.73 (0.07)
PM reflective - nasal congestion	-0.66 (0.06)	-0.82 (0.06)
PM reflective - nasal itching	-0.64 (0.07)	-0.85 (0.07)
PM reflective - sneezing	-0.65 (0.07)	-0.87 (0.06)

9. Secondary Outcome Measure:

Measure Title	Total Ocular Symptoms: Mean Change From Baseline Over the Entire Treatment Period in AM, Pre-dose Instantaneous Total Ocular Symptom Scores (iTOSS)

Measure Description	The AM, pre-dose iTOSS is the sum of the 3 individual ocular symptom scores for eyes itching/burning, eyes tearing/ watering, and eye redness, performed immediately prior to taking the daily dose; each symptom is scored on a scale of 0 (none) to 3 (severe), with a total possible score of 0 to 9. Change from baseline is calculated as the score at the end of study minus the score at baseline.
Time Frame	Daily; Baseline through End of Study (Week 4)
Safety Issue?	No

Analysis Population Description
ITT Population

Reporting Groups

	Description
Placebo	Placebo nasal spray
Fluticasone Furoate 110 mcg	Once-daily fluticasone furoate (FF) nasal spray 110 mcg

Measured Values

	Placebo	Fluticasone Furoate 110 mcg
Number of Participants Analyzed	155	160
Total Ocular Symptoms: Mean Change From Baseline Over the Entire Treatment Period in AM, Pre-dose Instantaneous Total Ocular Symptom Scores (iTOSS) [units: Points on a scale] Least Squares Mean (Standard Error)	-1.80 (0.20)	-1.97 (0.19)

10. Secondary Outcome Measure:

Measure Title	Total Ocular Symptoms: Mean Change From Baseline Over the Entire Treatment Period in Both the AM Reflective Total Ocular Symptom Scores (rTOSS) and PM rTOSS
Measure Description	The rTOSS is a rating of the severity of symptoms over the previous 12 hours and was performed in the AM (AM rTOSS) and PM (PM rTOSS). Change from baseline is calculated as the score at the end of study minus the score at baseline. Each symptom is scored on a scale of 0 (none) to 3 (severe), with a total possible score of 0 to 9.
Time Frame	Daily; Baseline through End of Study (Week 4)
Safety Issue?	No

Analysis Population Description
ITT Population

Reporting Groups

	Description
Placebo	Placebo nasal spray
Fluticasone Furoate 110 mcg	Once-daily fluticasone furoate (FF) nasal spray 110 mcg

Measured Values

	Placebo	Fluticasone Furoate 110 mcg
Number of Participants Analyzed	155	160
Total Ocular Symptoms: Mean Change From Baseline Over the Entire Treatment Period in Both the AM Reflective Total Ocular Symptom Scores (rTOSS) and PM rTOSS [units: Points on a scale] Least Squares Mean (Standard Error)		
AM rTOSS	-1.92 (0.20)	-2.19 (0.19)
PM rTOSS	-2.05 (0.20)	-2.28 (0.19)

11. Secondary Outcome Measure:

Measure Title	Total Ocular Symptoms: Mean Percent Change From Baseline Over the Entire Treatment Period in Both the Daily rTOSS and the AM, Pre-dose iTOSS
Measure Description	The rTOSS is a rating of the severity of symptoms over the previous 12 hours and was performed in the AM (AM rTOSS) and PM (PM rTOSS). AM, pre-dose iTOSS: sum of the 3 individual ocular symptom scores (scored on a scale of 0 [none] to 3 [severe], with a total possible score of 0 to 9) for eyes itching/burning, eyes tearing/watering, and eye redness, performed immediately prior to taking the daily dose. Change from baseline is calculated as the score at the end of study minus the score at baseline.
Time Frame	Daily; Baseline through End of Study (Week 4)
Safety Issue?	No

Analysis Population Description

ITT Population

Reporting Groups

	Description
Placebo	Placebo nasal spray

	Description
Fluticasone Furoate 110 mcg	Once-daily fluticasone furoate (FF) nasal spray 110 mcg

Measured Values

	Placebo	Fluticasone Furoate 110 mcg
Number of Participants Analyzed	155	160
Total Ocular Symptoms: Mean Percent Change From Baseline Over the Entire Treatment Period in Both the Daily rTOSS and the AM, Pre-dose iTOSS [units: percent change] Least Squares Mean (Standard Error)		
Daily rTOSS	-29.1 (2.39)	-32.1 (2.44)
AM, pre-dose iTOSS	-27.1 (2.54)	-29.7 (2.55)

12. Secondary Outcome Measure:

Measure Title	Individual Ocular Symptoms: Mean Change From Baseline Over the Entire Treatment Period in Both the Individual, Daily Reflective and the AM, Pre-dose Instantaneous Ocular Symptom Scores for Eyes Itching/Burning, Eyes Tearing/ Watering, and Eye Redness.
Measure Description	The rTOSS is a rating of the severity of symptoms over the previous 12 hrs. and was performed in the AM (AM rTOSS) and PM (PM rTOSS). The AM, pre-dose iTOSS is the sum of the 3 individual ocular symptom scores (scored on a scale of 0 [none] to 3 [severe], with a total possible score of 0 to 9) for eyes itching/burning, eyes tearing/watering, and eye redness, performed immediately prior to taking the daily dose. Change from baseline is calculated as the score at the end of study minus the score at baseline.
Time Frame	Daily; Baseline through End of Study (Week 4)
Safety Issue?	No

Analysis Population Description
ITT Population

Reporting Groups

	Description
Placebo	Placebo nasal spray
Fluticasone Furoate 110 mcg	Once-daily fluticasone furoate (FF) nasal spray 110 mcg

Measured Values

	Placebo	Fluticasone Furoate 110 mcg
Number of Participants Analyzed	155	160
Individual Ocular Symptoms: Mean Change From Baseline Over the Entire Treatment Period in Both the Individual, Daily Reflective and the AM, Pre-dose Instantaneous Ocular Symptom Scores for Eyes Itching/Burning, Eyes Tearing/Watering, and Eye Redness. [units: Points on a scale] Least Squares Mean (Standard Error)		
Daily reflective - eye itching/burning	-0.64 (0.07)	-0.75 (0.06)
Daily reflective - eye tearing/watering	-0.69 (0.07)	-0.76 (0.06)
Daily reflective - eye redness	-0.65 (0.07)	-0.72 (0.07)
AM, pre-dose iTOSS - eye itching/burning	-0.58 (0.07)	-0.67 (0.07)
AM, pre-dose iTNSS - eye tearing/watering	-0.63 (0.07)	-0.67 (0.07)
AM, pre-dose iTNSS - eye redness	-0.59 (0.07)	-0.63 (0.07)

13. Secondary Outcome Measure:

Measure Title	Mean Change From Baseline Over the Entire Treatment Period in Both the Individual AM Reflective and PM Reflective Ocular Symptom Scores for Eyes Itching/Burning, Eyes Tearing/Watering, and Eye Redness
Measure Description	The rTOSS is a rating of the severity of symptoms over the previous 12 hrs. and was performed in the AM (AM rTOSS) and PM (PM rTOSS). Each symptom is scored on a scale of 0 (none) to 3 (severe), with a total possible score of 0 to 9. Change from baseline is calculated as the score at the end of study minus the score at baseline.
Time Frame	Daily; Baseline through End of Study (Week 4)
Safety Issue?	No

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
Placebo	Placebo nasal spray

	Description
Fluticasone Furoate 110 mcg	Once-daily fluticasone furoate (FF) nasal spray 110 mcg

Measured Values

	Placebo	Fluticasone Furoate 110 mcg
Number of Participants Analyzed	155	160
Mean Change From Baseline Over the Entire Treatment Period in Both the Individual AM Reflective and PM Reflective Ocular Symptom Scores for Eyes Itching/Burning, Eyes Tearing/Watering, and Eye Redness [units: Points on a scale] Least Squares Mean (Standard Error)		
AM reflective - eye itching/burning	-0.62 (0.07)	-0.74 (0.07)
AM reflective - eye tearing/watering	-0.66 (0.07)	-0.74 (0.06)
AM reflective - eye redness	-0.63 (0.07)	-0.72 (0.07)
PM reflective - eye itching/burning	-0.66 (0.07)	-0.77 (0.07)
PM reflective - eye tearing/watering	-0.72 (0.07)	-0.79 (0.07)
PM reflective - eye redness	-0.67 (0.07)	-0.73 (0.07)

14. Secondary Outcome Measure:

Measure Title	Peak Nasal Inspiratory Flow (PNIF): Mean Change From Baseline in Daily, AM, and PM PNIF
Measure Description	PNIF: Objective measure of nasal airway flow obstruction.
Time Frame	Daily; Baseline through End of Study (Week 4)
Safety Issue?	No

Analysis Population Description
ITT Population

Reporting Groups

	Description
Placebo	Placebo nasal spray

	Description
Fluticasone Furoate 110 mcg	Once-daily fluticasone furoate (FF) nasal spray 110 mcg

Measured Values

	Placebo	Fluticasone Furoate 110 mcg
Number of Participants Analyzed	155	160
Peak Nasal Inspiratory Flow (PNIF): Mean Change From Baseline in Daily, AM, and PM PNIF [units: Liters/minute] Least Squares Mean (Standard Error)		
PNIF: daily	13.52 (2.29)	19.98 (2.20)
PNIF: AM	13.15 (2.36)	19.67 (2.27)
PNIF: PM	13.88 (2.38)	20.05 (2.28)

15. Secondary Outcome Measure:

Measure Title	Mean Change From Baseline to Endpoint in the Rhinoconjunctivitis Quality of Life Questionnaire With Standardised Activities (RQLQ[S])
Measure Description	RQLQ(S) is a 28-item, self-administered, disease-specific (allergic rhinitis), quality of life instrument that assesses quality of life over a 1-week interval. Each question is scored from 0 (not impaired at all) to 6 (severely impaired), with higher scores indicating more impairment on quality of life. RQLQ(S): Possible score ranges from 0 to 6. Change from baseline is calculated as the score at the endpoint minus the score at baseline.
Time Frame	Baseline and Week 4
Safety Issue?	No

Analysis Population Description
ITT Population

Reporting Groups

	Description
Placebo	Placebo nasal spray
Fluticasone Furoate 110 mcg	Once-daily fluticasone furoate (FF) nasal spray 110 mcg

Measured Values

	Placebo	Fluticasone Furoate 110 mcg
Number of Participants Analyzed	155	160
Mean Change From Baseline to Endpoint in the Rhinoconjunctivitis Quality of Life Questionnaire With Standardised Activities (RQLQ[S]) [units: Points on a scale] Least Squares Mean (Standard Error)	-1.22 (0.18)	-1.76 (0.16)

Reported Adverse Events

Time Frame	[Not specified]
Additional Description	[Not specified]

Reporting Groups

	Description
Placebo	Placebo nasal spray
Fluticasone Furoate 110 mcg	Once-daily fluticasone furoate (FF) nasal spray 110 mcg

Serious Adverse Events

	Placebo	Fluticasone Furoate 110 mcg
	Affected/At Risk (%)	Affected/At Risk (%)
Total	0/155 (0%)	0/160 (0%)

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 5%

	Placebo	Fluticasone Furoate 110 mcg
	Affected/At Risk (%)	Affected/At Risk (%)
Total	22/155 (14.19%)	24/160 (15%)
Infections and infestations		
Nasopharyngitis [A] †	2/155 (1.29%)	8/160 (5%)

	Placebo	Fluticasone Furoate 110 mcg
	Affected/At Risk (%)	Affected/At Risk (%)
Nervous system disorders		
Headache [A] †	9/155 (5.81%)	8/160 (5%)
Respiratory, thoracic and mediastinal disorders		
Epistaxis [A] †	13/155 (8.39%)	24/160 (15%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA

Limitations and Caveats

[Not specified]

More Information

Certain Agreements:

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

GSK agreements may vary with individual investigators, but will not prohibit any investigator from publishing. GSK supports the publication of results from all centers of a multi-center trial but requests that reports based on single-site data not precede the primary publication of the entire clinical trial.

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