ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: 06/11/2015

ClinicalTrials.gov ID: NCT00296491

Study Identification

Unique Protocol ID:	ADA103575
Brief Title:	Study Of Allergic Rhinitis In Patients Who Also Have Asthma
Official Title:	A Multicenter, Randomized, Double-Blind, Triple-Dummy, Placebo-Controlled, Parallel Group, Four-Week Study Assessing the Efficacy of Fluticasone Propionate Aqueous Nasal Spray 200mcg QD Versus Montelukast 10mg QD in Adolescent and Adult Subjects With Asthma and Seasonal Allergic Rhinitis Who Are Receiving ADVAIR DISKUS® 100/50mcg BID or Placebo BID
Secondary IDs:	

Study Status

Record Verification:	June 2015
Overall Status:	Completed
Study Start:	September 2005
Primary Completion:	October 2007 [Actual]
Study Completion:	October 2007 [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: 50,703 Serial Number: 0654 Has Expanded Access? No
Review Board:	Approval Status: Board Name: Board Affiliation: Phone: Email: NA@NA.com
Data Monitoring?:	
Plan to Share Data?:	
Oversight Authorities:	United States: Food and Drug Administration

Study Description

Brief Summary:	This study will last up to 6 weeks. Subjects will visit the clinic up to 5 times. Certain clinic visits will include a physical examination, medical history review, and lung function tests. All study related medications and medical examinations will be provided at no cost to the subject. The drugs used in this study are approved for the age group under study.
Detailed Description:	A Multicenter, Randomized, Double-Blind, Triple-Dummy, Placebo-Controlled, Parallel Group, Four-Week Study Assessing the Efficacy of Fluticasone Propionate Aqueous Nasal Spray 200mcg QD versus Montelukast 10mg QD in Adolescent and Adult Subjects with Asthma and Seasonal Allergic Rhinitis Who are Receiving ADVAIR DISKUS® 100/50mcg BID or Placebo BID

Conditions

Conditions:	Asthma
Keywords:	Asthma Allergic Rhinitis

Study Design

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

Intervention Model:	Parallel Assignment
Number of Arms:	4
Masking:	Double Blind (Subject, Investigator)
Allocation:	Randomized
Endpoint Classification:	Safety/Efficacy Study
Enrollment:	725 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Active Comparator: Fluticasone Propionate/Salmeterol/Montelukast (FSC +MON) Fluticasone propionate/salmeterol DISKUS combination product (FSC) twice daily (BID) plus vehicle placebo nasal spray once daily (QD) plus montelukast capsule 10mg (MON) QD	Drug: fluticasone propionate/salmeterol (FSC) fluticasone propionate/salmeterol DISKUS combination Drug: montelukast (MON) montelukast capsule Drug: placebo nasal vehicle placebo nasal spray Drug: ADVAIR DISKUS ADVAIR DISKUS
Active Comparator: Fluticasone Propionate/Salmeterol (FSC) FSC BID plus vehicle placebo nasal spray QD plus placebo capsule QD	Drug: fluticasone propionate/salmeterol (FSC) fluticasone propionate/salmeterol DISKUS combination Drug: placebo nasal vehicle placebo nasal spray Drug: ADVAIR DISKUS ADVAIR DISKUS Drug: placebo capsule placebo capsule
Active Comparator: Fluticasone Prop/Salmeterol/Flut Prop Nasal Spray (FSC +FPANS) Fluticasone propionate/salmeterol DISKUS combination product (FSC)100/50mcg BID plus fluticasone propionate aqueous nasal spray 200mcg (FPANS) QD plus placebo capsule QD	Drug: fluticasone propionate/salmeterol (FSC) fluticasone propionate/salmeterol DISKUS combination Drug: fluticasone propionate (FP) fluticasone propionate aqueous nasal spray Drug: ADVAIR DISKUS ADVAIR DISKUS Drug: placebo capsule placebo capsule
Active Comparator: Montelukast (MON) Placebo DISKUS BID plus vehicle placebo nasal spray QD plus MON QD	Drug: montelukast (MON) montelukast capsule Drug: placebo nasal vehicle placebo nasal spray Drug: placebo DISKUS placebo DISKUS

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 15 Years

Maximum Age:

Gender: Both

Accepts Healthy Volunteers?: No

Criteria: INCLUSION CRITERIA:

A subject will be considered eligible for inclusion in this study only if all of the following criteria apply:

- Consent: A signed and dated written informed consent must be obtained from the subject or subject's legally acceptable representative prior to study participation. An informed consent must be signed prior to any change in the subject's medication regimen, including withholding medications prior to Visit 1.
- Gender: Male or female. Females are eligible to participate only if they are currently not pregnant and not lactating. Females of child-bearing potential will be required to use a highly effective method for avoiding pregnancy (i.e., contraception with a failure rate of <1% per year). Female subjects of child-bearing potential will undergo a urine pregnancy test at Visits 1, 2, 3, and 4. Any female who becomes pregnant during the study will be withdrawn. Female subjects should not be enrolled if they plan to become pregnant during the time of study participation.
- Age: 15 years and older.
- Asthma Diagnosis: A diagnosis of persistent asthma, for at least three months, as defined by the following American Thoracic Society definition:

Asthma is a clinical syndrome characterized by increased responsiveness of the tracheobronchial tree to a variety of stimuli. The major symptoms of asthma are paroxysms of dyspnea, wheezing, and cough, which may vary from mild and almost undetectable to severe and unremitting (status asthmaticus). The primary physiological manifestation of this hyperresponsiveness is variable airway obstruction. This can take the form of spontaneous fluctuations in the severity of obstruction, substantial improvements in the severity of obstruction following bronchodilators or corticosteroids, or increased obstruction caused by drugs or other stimuli [American Thoracic Society, 1987a].

NOTE: Intermittent and seasonal asthma, as well as exercise-induced bronchospasm alone, are excluded.

- Asthma Therapy: 3 months' prior and current use of one of the following asthma therapies, with no change in regimen during the month prior to Visit 1:
    - Scheduled or as-needed inhaled or oral short-acting beta2-agonist (SABA). Subjects must be able to replace their current short-acting beta2-agonist with albuterol/salbutamol, to be used only on an as-needed basis for the duration of the study.
    - Allowed non-corticosteroid controller therapy (e.g., anticholinergics and cromolyn).
    - One of the following inhaled corticosteroids taken at the corresponding daily dose:

criteria.

Inhaled Corticosteroid (Total Daily Dose) Beclomethasone dipropionate (≤420mcg) Beclomethasone dipropionate HFA (≤240mcg) Budesonide (≤400mcg) Flunisolide (≤1000mcg) Fluticasone propionate inhalation aerosol (≤220mcg) Fluticasone propionate inhalation powder (≤250mcg) Mometasone furoate (≤220mcg) Triamcinolone acetonide (≤1000mcg) Subjects taking ADVAIR 100/50mcg BID are eligible to replace ADVAIR with FLOVENT HFA 110mcg BID for 14 days prior to Visit 1. This change will be at the Investigator's clinical discretion, taking each individual's current and past asthma stability into account. The subject must be aware of the risks and benefits of switching their medication and acknowledge this by signing an informed consent prior to any change in the subject's medication regimen.

- Asthma Severity: An FEV1 between 65% - 95% of predicted value at Visit 1 after withholding asthma medications as detailed in the protocol.

At Visit 2, subjects must also be experiencing minimum asthma symptoms as defined in Section 5.2.3, "Randomization Criteria", and in Section 6.2 of the protocol.

Predicted FEV1 will be based on the National Health and Nutrition Examination Survey (NHANES III) predicted normal values [Hankinson, 1999].

- Rhinitis Diagnosis: A diagnosis of seasonal allergic rhinitis defined as follows:
    - A clinical history (written or verbal confirmation) of allergic rhinitis with the seasonal onset and offset of nasal allergy symptoms during each of the previous 2 relevant allergy seasons (captured in source documents only).

AND •A positive skin test reaction to a geographically relevant seasonal allergen, as determined by the skin prick method, within 24 months prior to or at Visit 1.

For the purposes of this study, a positive skin test reaction is defined as a wheal diameter that is at least 3mm greater than diluent control using 1:20 W:V glycerinated solution.

•At Visit 2, subjects must also be experiencing minimum rhinitis symptoms as defined in Section 5.2.3, "Randomization Criteria", and in Section 6.2 of the protocol.

- Geographical Location: Active residence within a geographical region where exposure to a relevant seasonal allergen is expected to be significant during the entire study period.

Note: The principal investigator is responsible for tracking and recording pollen counts for geographically relevant seasonal allergens throughout the entire study. Alternatively, this information may be obtained from a reputable source from within the same geographical area.

EXCLUSION CRITERIA:

A subject will not be eligible for inclusion in this study if any of the following criteria apply:

- Currently Diagnosed with Life-Threatening Asthma: An episode or episodes of asthma requiring intubation associated with hypercapnia, respiratory arrest, or hypoxic seizures.
- Asthma Instability: Hospitalization for asthma within 6 months of Visit 1.
- Concurrent Respiratory Disease: Current evidence of pneumonia, pneumothorax, atelectasis, pulmonary fibrotic disease, chronic bronchitis, emphysema, or any other respiratory abnormalities other than asthma.
- Nasal Obstruction: Severe physical obstruction of the nose (e.g., deviated septum) that could affect the deposition of double-blind intranasal study drug.
- Nasal History: History of nasal septal perforation or recent nasal septal surgery.

- Other Concurrent Conditions/Diseases: Any evidence of rhinitis medicamentosa, history of glaucoma and/or cataracts or ocular herpes simplex, or any clinically significant, uncontrolled condition or disease state that, in the opinion of the investigator, would put the safety of the subject at risk through study participation or would confound the interpretation of the results if the condition/disease exacerbated during the study.

The list of additional excluded conditions/diseases includes, but is not limited to: cardiac arrhythmias; congestive heart failure; coronary artery disease; poorly controlled diabetes, poorly controlled hypertension, poorly controlled peptic ulcer, hematologic, hepatic, or renal disease; immunologic compromise; current malignancy; current or quiescent tuberculosis, and Cushing's or Addison's disease.

- Drug Allergy: Any immediate or delayed hypersensitivity to any beta2-agonist, sympathomimetic drug, leukotriene modifier, or any intranasal, inhaled, or systemic corticosteroid therapy, or sensitivity to aspirin or other NSAIDS. Subjects with severe milk protein allergies are also excluded from participation.
- Respiratory Tract Infections: Any sinus, middle ear, oropharyngeal, upper or lower respiratory tract infection that has not resolved at least 14 days immediately preceding Visit 1, or for which antibiotic therapy has not been completed at least 14 days prior to Visit 1.
- Concurrent Medications: Concurrent use of any of the following medications that may affect the course of asthma, rhinitis, or interact with sympathomimetic amines or montelukast.
    - Beta-blockers
    - tricyclic antidepressants
    - monoamine oxidase inhibitors
    - phenobarbital
    - rifampin
    - ritonavir
    - ketoconazole
- Systemic Corticosteroids: Use of oral or parenteral systemic corticosteroids within 28 days of Visit 1, or requirement for more than two courses of parenteral systemic corticosteroids for asthma within 6 months of Visit 1.

NOTE: Topical hydrocortisone cream or ointment (1% or less) is permitted during the study.

- Excluded Rhinitis Medications: The following rhinitis medications must be withheld during the corresponding "exclusion period" prior to Visit 1 and are not allowed any time during the study, unless dispensed as double-blind study drug:

Medication (Exclusion Period Prior to Visit 1) Intranasal and ocular corticosteroids (28 days) Leukotriene modifiers (e.g., Singulair, Accolate, Zyflo) (28 days) Intranasal and ocular cromolyn (14 days) Long-acting antihistamines (e.g., loratadine, cetirizine) (10 days) Short-acting antihistamines (includes prescription and OTC) (72 hours) Oral and intranasal decongestants (72 hours) Intranasal anticholinergics (e.g., Atrovent) (24 hours)

- Excluded Asthma Medications: The following asthma medications must be withheld during the corresponding "exclusion period" prior to Visit 1.

These asthma medications, with the exception of an inhaled corticosteroid/long-acting beta2-agonist combination product and Xolair, may be continued during the run-in period of the study (between Visits 1 and 2), but must be withheld prior to Visit 2 for the appropriate "exclusion period" as shown below.

These asthma medications are not allowed any time after randomization at Visit 2 (with the exception of as as-needed rescue albuterol/salbutamol), unless dispensed as double-blind study drug:

Medication[a] (Exclusion Period Prior to Visit 1 and/or Visit 2) Inhaled corticosteroid/long-acting beta2-agonist combination product (e.g., ADVAIR) (14 days) Inhaled anticholinergics (e.g., Atrovent, Combivent, Spiriva) (24 hours) Theophylline products (48 hours) Inhaled cromolyn or nedocromil (24 hours) Inhaled corticosteroids (12 hours) Long-acting beta2-agonists (e.g., Foradil, SEREVENT™) (14 days) Oral beta2-agonists (12 hours) Inhaled short-acting beta2-agonists^b (e.g., Proventil) (6 hours) Xolair (12 months)

a. For the leukotriene modifier "exclusion period" prior to Visit 1, refer to Exclusion Criterion 11.
b. Replaced at Visit 1 with albuterol/salbutamol.

- Ophthalmic preparations: Use of artificial tears, eyewashes, homeopathic preparations, irrigation solutions, lubricants, sympathomimetic preparations, vasoconstrictors, or combinations of any of the aforementioned products during the study.
- Immunosuppressive Medications: Use of immunosuppressive medications during the study.

NOTE: Immunotherapy for the treatment of allergies is allowed during the study, provided that it was not initiated within 30 days of Visit 1, 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.

- Positive Pregnancy Test: A positive pregnancy test at Visit 1.
- Tobacco Use: Greater than a 10 pack-year history of cigarette smoking or use of any tobacco products within 1 year of Visit 1. This includes cigarettes, cigars, pipe, chewing tobacco, and snuff.

Note: Pack years = number of cigarettes smoked per day divided by 20, multiplied by the number of years of smoking.

- Questionable Validity of Consent: Any infirmity or disability that would limit the subject's consent or geographic location that would limit the compliance for scheduled visits.
- Investigational Medications: Use of any investigational drug within 30 days of Visit 1.
- 3rd shift/Nighttime employment: Any employment during the nighttime hours (10 p.m. - 6 a.m.) or 3rd shift.
- Site affiliation: Participation of anyone associated with the administration of the study or their immediate family members

Contacts/Locations

Study Officials: GSK Clinical Trials
Study Director
GlaxoSmithKline

Locations: United States, Ohio
GSK Investigational Site
Cincinnati, Ohio, United States, 45242

United States, Missouri
GSK Investigational Site
Warrensburg, Missouri, United States, 64093

GSK Investigational Site
Rolla, Missouri, United States, 65401

United States, Colorado
GSK Investigational Site
Colorado Springs, Colorado, United States, 80907

United States, California
GSK Investigational Site
Berkeley, California, United States, 94705

United States, Alabama
GSK Investigational Site
Birmingham, Alabama, United States, 35209

United States, Kansas
GSK Investigational Site
Overland Park, Kansas, United States, 66210

United States, Arizona
GSK Investigational Site
Glendale, Arizona, United States, 85304

United States, Nebraska
GSK Investigational Site
Lincoln, Nebraska, United States, 68505

United States, Maryland
GSK Investigational Site
Baltimore, Maryland, United States, 21236

Poland
GSK Investigational Site
Krakow, Poland, 31-023

United States, Nebraska
GSK Investigational Site
Omaha, Nebraska, United States, 68131

GSK Investigational Site
Papillion, Nebraska, United States, 68046

United States, Texas
GSK Investigational Site
Dallas, Texas, United States, 75231-4307

United States, Florida
GSK Investigational Site
Ocala, Florida, United States, 34471

United States, New York
GSK Investigational Site
Rochester, New York, United States, 14618

United States, Ohio
GSK Investigational Site
Canton, Ohio, United States, 44718

Canada, Ontario
GSK Investigational Site
Ottawa, Ontario, Canada, K1N 6N5

United States, California
GSK Investigational Site
Rancho Mirage, California, United States, 92270

United States, Tennessee
GSK Investigational Site
Knoxville, Tennessee, United States, 37909

United States, Georgia
GSK Investigational Site
Columbus, Georgia, United States, 31904

United States, California
GSK Investigational Site
San Jose, California, United States, 95128

United States, Colorado
GSK Investigational Site
Colorado Springs, Colorado, United States, 80907

Estonia
GSK Investigational Site
Tallinn, Estonia, 13419

United States, Illinois
GSK Investigational Site
Chicago, Illinois, United States, 60612

United States, Texas
GSK Investigational Site
Houston, Texas, United States, 77070

United States, Missouri
GSK Investigational Site

St. Louis, Missouri, United States, 63141

United States, Texas
GSK Investigational Site
Waco, Texas, United States, 76708

Canada, Ontario
GSK Investigational Site
Niagara Falls, Ontario, Canada, L2G 1J4

United States, Washington
GSK Investigational Site
Kirkland, Washington, United States, 98034

United States, California
GSK Investigational Site
San Diego, California, United States, 92120

United States, Texas
GSK Investigational Site
Dallas, Texas, United States, 75246

United States, Pennsylvania
GSK Investigational Site
Upland, Pennsylvania, United States, 19013

Poland
GSK Investigational Site
Bialystok, Poland, 15-274

Canada, Ontario
GSK Investigational Site
Sudbury, Ontario, Canada, P3E 1H5

United States, California
GSK Investigational Site
Los Angeles, California, United States, 90025

GSK Investigational Site
Riverside, California, United States, 92506

Canada, Manitoba
GSK Investigational Site
Winnipeg, Manitoba, Canada, R3C 0N2

United States, New Jersey

GSK Investigational Site
Forked River, New Jersey, United States, 08731

Canada, Ontario
GSK Investigational Site
Ottawa, Ontario, Canada, K2C 3R2

United States, Oregon
GSK Investigational Site
Portland, Oregon, United States, 97213

United States, Ohio
GSK Investigational Site
Parma, Ohio, United States, 44129

United States, Kentucky
GSK Investigational Site
Owensboro, Kentucky, United States, 42301

United States, South Carolina
GSK Investigational Site
Orangeburg, South Carolina, United States, 29118

United States, Virginia
GSK Investigational Site
Danville, Virginia, United States, 24541

GSK Investigational Site
Richmond, Virginia, United States, 23298

United States, Nebraska
GSK Investigational Site
Omaha, Nebraska, United States, 68124

United States, California
GSK Investigational Site
San Diego, California, United States, 92120

United States, Texas
GSK Investigational Site
San Antonio, Texas, United States, 78233

Canada, Ontario
GSK Investigational Site
Brampton, Ontario, Canada, L6T 3T1

United States, Missouri
GSK Investigational Site
Jefferson City, Missouri, United States, 65101

United States, Oklahoma
GSK Investigational Site
Oklahoma City, Oklahoma, United States, 73120

United States, New Jersey
GSK Investigational Site
Summit, New Jersey, United States, 07091

United States, Kentucky
GSK Investigational Site
Louisville, Kentucky, United States, 40215

United States, Mississippi
GSK Investigational Site
Jackson, Mississippi, United States, 39202

United States, Texas
GSK Investigational Site
Houston, Texas, United States, 77054

GSK Investigational Site
San Antonio, Texas, United States, 78205

United States, California
GSK Investigational Site
Huntington Beach, California, United States, 92647

Canada, Quebec
GSK Investigational Site
Trois Rivières, Quebec, Canada, G8T 7A1

United States, Colorado
GSK Investigational Site
Fort Collins, Colorado, United States, 80526

United States, Utah
GSK Investigational Site
West Jordan, Utah, United States, 84084

United States, South Carolina
GSK Investigational Site
Simpsonville, South Carolina, United States, 29681

Estonia
GSK Investigational Site
Tartu, Estonia, 51014

United States, Louisiana
GSK Investigational Site
Baton Rouge, Louisiana, United States, 70808

United States, Arizona
GSK Investigational Site
Scottsdale, Arizona, United States, 85251

United States, Kentucky
GSK Investigational Site
Lexington, Kentucky, United States, 40536

United States, Nebraska
GSK Investigational Site
Omaha, Nebraska, United States, 68130

United States, Oregon
GSK Investigational Site
Bend, Oregon, United States, 97701

Canada, Ontario
GSK Investigational Site
Ajax, Ontario, Canada, L1S 2J5

United States, Texas
GSK Investigational Site
Kerrville, Texas, United States, 78028

United States, Georgia
GSK Investigational Site
Savannah, Georgia, United States, 31406

United States, Texas
GSK Investigational Site
San Antonio, Texas, United States, 78229

Canada, Ontario
GSK Investigational Site
Mississauga, Ontario, Canada, L5A 3V4

United States, California
GSK Investigational Site

Vista, California, United States, 92083

United States, Louisiana
GSK Investigational Site
Shreveport, Louisiana, United States, 71105

United States, California
GSK Investigational Site
San Diego, California, United States, 92103

United States, Florida
GSK Investigational Site
Brandon, Florida, United States, 33511

United States, Texas
GSK Investigational Site
Austin, Texas, United States, 78750

GSK Investigational Site
San Antonio, Texas, United States, 78229

United States, Indiana
GSK Investigational Site
South Bend, Indiana, United States, 46617

United States, Georgia
GSK Investigational Site
Albany, Georgia, United States, 31707

GSK Investigational Site
Gainesville, Georgia, United States, 30501

United States, Texas
GSK Investigational Site
El Paso, Texas, United States, 79925

United States, Tennessee
GSK Investigational Site
Chattanooga, Tennessee, United States, 37421

United States, California
GSK Investigational Site
Roseville, California, United States, 95678

Poland
GSK Investigational Site

Lodz, Poland, 93-513

United States, Florida
GSK Investigational Site
Pensacola, Florida, United States, 32504

United States, Louisiana
GSK Investigational Site
Lafayette, Louisiana, United States, 70503

GSK Investigational Site
Covington, Louisiana, United States, 70433

United States, South Carolina
GSK Investigational Site
Greenville, South Carolina, United States, 29607

United States, Tennessee
GSK Investigational Site
Savannah, Tennessee, United States, 38372

United States, Texas
GSK Investigational Site
San Antonio, Texas, United States, 78229

United States, Georgia
GSK Investigational Site
Savannah, Georgia, United States, 31405

United States, South Carolina
GSK Investigational Site
Charleston, South Carolina, United States, 29407

GSK Investigational Site
Spartanburg, South Carolina, United States, 29303

Canada, Quebec
GSK Investigational Site
Quebec City, Quebec, Canada, G1V 4M6

United States, Texas
GSK Investigational Site
Dallas, Texas, United States, 75230

United States, Louisiana
GSK Investigational Site

Sunset, Louisiana, United States, 70584

United States, Iowa
GSK Investigational Site
Iowa City, Iowa, United States, 52242

United States, Pennsylvania
GSK Investigational Site
Pittsburgh, Pennsylvania, United States, 15241

United States, North Carolina
GSK Investigational Site
Asheville, North Carolina, United States, 28801

United States, California
GSK Investigational Site
Long Beach, California, United States, 90806

GSK Investigational Site
Stockton, California, United States, 95207

United States, Colorado
GSK Investigational Site
Lakewood, Colorado, United States, 80401

United States, Florida
GSK Investigational Site
Tallahassee, Florida, United States, 32308

United States, Illinois
GSK Investigational Site
Springfield, Illinois, United States, 62704

United States, Tennessee
GSK Investigational Site
Germantown, Tennessee, United States, 38138

United States, Texas
GSK Investigational Site
Dallas, Texas, United States, 75240

United States, Colorado
GSK Investigational Site
Boulder, Colorado, United States, 80304

United States, Rhode Island

GSK Investigational Site
Providence, Rhode Island, United States, 02906

United States, California
GSK Investigational Site
San Jose, California, United States, 95117

United States, Texas
GSK Investigational Site
San Antonio, Texas, United States, 78229

Poland
GSK Investigational Site
Bialystok, Poland, 15-025

United States, North Carolina
GSK Investigational Site
Raleigh, North Carolina, United States, 27607

United States, Georgia
GSK Investigational Site
Atlanta, Georgia, United States, 30342

Canada, Ontario
GSK Investigational Site
Kanata, Ontario, Canada, K2L 3C8

United States, Massachusetts
GSK Investigational Site
North Andover, Massachusetts, United States, 01845

United States, Minnesota
GSK Investigational Site
Minneapolis, Minnesota, United States, 55402

United States, Texas
GSK Investigational Site
El Paso, Texas, United States, 79902

United States, Arizona
GSK Investigational Site
Tucson, Arizona, United States, 85712

United States, Arkansas
GSK Investigational Site
Hot Springs, Arkansas, United States, 71913

United States, Indiana
GSK Investigational Site
Indianapolis, Indiana, United States, 46208

United States, Utah
GSK Investigational Site
Salt Lake City, Utah, United States, 84121

Estonia
GSK Investigational Site
Tartu, Estonia, 51014

United States, Florida
GSK Investigational Site
Coral Gables, Florida, United States, 33134

United States, South Carolina
GSK Investigational Site
Charleston, South Carolina, United States, 29414

United States, Georgia
GSK Investigational Site
Lawrenceville, Georgia, United States, 30045

References

Citations:

Links:

Study Data/Documents:

Study Results

Participant Flow

Reporting Groups

	Description
Flut Prop/Salmeterol/Flut Prop Nasal Spray (FSC+FPANS)	Flut Prop = Fluticasone Propionate.

	Description
Fluticasone Propionate/Salmeterol/ Montelukast (FSC+MON)	
Fluticasone Propionate/Salmeterol (FSC)	
Montelukast (MON)	

Overall Study

	Flut Prop/ Salmeterol/Flut Prop Nasal Spray (FSC+FPANS)	Fluticasone Propionate/ Salmeterol/ Montelukast (FSC+MON)	Fluticasone Propionate/ Salmeterol (FSC)	Montelukast (MON)
Started	182 [1]	182	180	181
Completed	140	129	137	138
Not Completed	42	53	43	43
Low Pollen Counts	18	26	25	16
Protocol Violation	4	6	2	3
Adverse Event	1	3	1	4
Withdrawn due to Asthma	0	0	0	4
Withdrawal by Subject	7	3	3	2
Non-Compliance	12	13	10	14
Lost to Follow-up	0	2	2	0

[1] Please note: Outcome Measures generally conducts analysis of 2 of the 4 Arms at a time.

Baseline Characteristics

Reporting Groups

	Description
Fluticasone Propionate/Salmeterol/ Montelukast (FSC+MON)	Fluticasone Propionate/Salmeterol/Montelukast (FSC+MON) = FSC twice a day (BID), plus vehicle placebo nasal spray once a day (QD), plus MON once a day (QD)

	Description
Fluticasone Propionate/Salmeterol (FSC)	Fluticasone Propionate/Salmeterol (FSC) = FSC BID, plus vehicle placebo nasal spray once a day (QD), plus placebo capsule once a day (QD).
Fluticasone Prop/Salmeterol/Flut Prop Nasal Spray (FSC+FPANS)	Fluticasone Prop/Salmeterol/Flut Prop Nasal Spray (FSC+FPANS) = FSC twice a day (BID), plus FPANS (once a day) QD, plus placebo capsule once a day (QD).
Montelukast (MON)	Montelukast (MON) = Placebo DISKUS BID, plus vehicle placebo nasal spray once a day (QD), plus MON (once a day) QD.

Baseline Measures

	Fluticasone Propionate/ Salmeterol/Montelukast (FSC+MON)	Fluticasone Propionate/ Salmeterol (FSC)	Fluticasone Prop/ Salmeterol/Flut Prop Nasal Spray (FSC+FPANS)	Montelukast (MON)	Total
Number of Participants	182	180	182	181	725
Age, Continuous [units: years] Mean (Standard Deviation)	33.0 (13.54)	34.5 (14.64)	34.9 (12.62)	34.5 (12.47)	34.2 (13.34)
Gender, Male/Female [units: participants]					
Female	115	102	120	112	449
Male	67	78	62	69	276
Race/Ethnicity, Customized [units: participants]					
White	138	138	143	145	564
African American/African Heritage	34	35	31	30	130
American Indian or Alaska Native	0	1	1	0	2
Asian	9	5	5	5	24
Native Hawaiian or other Pacific Islander	1	1	1	1	4
Unknown	0	0	1	0	1

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Mean Change From Baseline at Endpoint in Morning Peak Expiration Flow (PEF) for Intent-to-Treat Population
Measure Description	Endpoint was defined as the average of the data reported from the last week of treatment. Data collected by patient throughout the treatment period between visits. The peak expiratory flow rate measures how fast a person can breathe out (exhale) air. It is one of many tests that measure how well your airways work.
Time Frame	Baseline to Endpoint (weeks 3-4)
Safety Issue?	No

Analysis Population Description

The Intent-to-Treat (ITT) population, the basis for superiority comparisons between FSC and MON in the context of asthma measures, included all subjects randomized to double-blind treatment.

Reporting Groups

	Description
Fluticasone Prop/Salmeterol (FSC)	
Montelukast (MON)	

Measured Values

	Fluticasone Prop/Salmeterol (FSC)	Montelukast (MON)
Number of Participants Analyzed	179	181
Mean Change From Baseline at Endpoint in Morning Peak Expiration Flow (PEF) for Intent-to-Treat Population [units: L/min] Mean (Standard Error)	26.4 (4.10)	3.6 (3.28)

Statistical Analysis 1 for Mean Change From Baseline at Endpoint in Morning Peak Expiration Flow (PEF) for Intent-to-Treat Population

Statistical Analysis Overview	Comparison Groups	Fluticasone Prop/Salmeterol (FSC), Montelukast (MON)
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	<0.001
	Comments	[Not specified]
	Method	t-test, 2 sided
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Mean Difference (Net)
	Estimated Value	23.2
	Confidence Interval	(2-Sided) 95% 12.5 to 33.8
	Parameter Dispersion	Type: Standard Error of the mean Value: 5.41
	Estimation Comments	Treatment Difference = FSC - MON

2. Primary Outcome Measure:

Measure Title	Mean Change From Baseline at Endpoint in Morning Peak Expiratory Flow (PEF) for Per Protocol Population
Measure Description	Endpoint was defined as the average of the data reported from the last week of treatment. Data collected by patient throughout the treatment period between visits. The peak expiratory flow rate measures how fast a person can breathe out (exhale) air. It is one of many tests that measure how well your airways work.
Time Frame	Baseline to Endpoint (weeks 3-4)
Safety Issue?	No

Analysis Population Description

The Per Protocol population, the basis for equivalence comparison between FSC and FSC+MON in terms of asthma measures, included subjects from the ITT population who did not deviate significantly from the protocol.

Reporting Groups

	Description
Flut Prop/Salmeterol/Montelukast (FSC+MON)	
Fluticasone Propionate/Salmeterol (FSC)	

Measured Values

	Flut Prop/Salmeterol/ Montelukast (FSC+MON)	Fluticasone Propionate/Salmeterol (FSC)
Number of Participants Analyzed	83	88
Mean Change From Baseline at Endpoint in Morning Peak Expiratory Flow (PEF) for Per Protocol Population [units: L/min] Mean (Standard Error)	30.9 (4.92)	35.2 (6.41)

Statistical Analysis 1 for Mean Change From Baseline at Endpoint in Morning Peak Expiratory Flow (PEF) for Per Protocol Population

Statistical Analysis Overview	Comparison Groups	Flut Prop/Salmeterol/Montelukast (FSC+MON), Fluticasone Propionate/Salmeterol (FSC)
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	Yes
	Comments	Given estimates, and assuming a significance level of a=0.05, a sample size of 133 subjects per treatment was determined to be sufficient to provide 80% power to show equivalance.

Statistical Test of Hypothesis	P-Value	<0.127
	Comments	[Not specified]
	Method	t-test, 2 sided
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Mean Difference (Net)
	Estimated Value	-8.9
	Confidence Interval	(2-Sided) 95% -24.6 to 6.9
	Parameter Dispersion	Type: Standard Error of the mean Value: 8.00
	Estimation Comments	Treatment Difference=FSC+MON-FSC

3. Secondary Outcome Measure:

Measure Title	Rhinitis: Mean Change From Baseline at 1-2 Weeks in Daytime Total Nasal Symptom Scores (D-TNNS).

Measure Description	The sum of scores of each of the four daytime symptoms (nasal congestion, itching, rhinorrhea, and sneezing). Scale: 0=none (no sign/symptom evident)1=mild (sign/symptom clearly present; easily tolerated)2=moderate (definite awareness of sign/symptom that is bothersome but tolerable)3=severe (sign/symptom is hard to tolerate)
Time Frame	Baseline to 1-2 Weeks
Safety Issue?	No

Analysis Population Description

The Intent-to-Treat (ITT) population, the basis for superiority comparisons between FSC+FPANS and FSC+MON in the context of rhinitis measures, included all subjects randomized to double-blind treatment. Families of secondary efficacy measures were each adjusted for multiplicity using Hochberg's method.

Reporting Groups

	Description
Fluticasone Prop/Salmeterol/ Montelukast (FSC+MON)	
Fluticasone Prop/Salmeterol/Flut Nasal Spray (FSC+FPANS)	

Measured Values

	Fluticasone Prop/Salmeterol/ Montelukast (FSC+MON)	Fluticasone Prop/Salmeterol/ Flut Nasal Spray (FSC+FPANS)
Number of Participants Analyzed	181	181
Rhinitis: Mean Change From Baseline at 1-2 Weeks in Daytime Total Nasal Symptom Scores (D-TNNS). [units: Points on a Scale] Mean (Standard Error)	-2.3 (0.16)	-3.0 (0.18)

4. Secondary Outcome Measure:

Measure Title	Rhinitis: Mean Change From Baseline at 1-2 Weeks in Nighttime Total Nasal Symptom Scores (N-TNSS)
Measure Description	The scores of 3 nighttime symptoms (nasal congestion upon awakening, difficulty going to sleep due to nasal symptoms, nighttime awakenings due to nasal symptoms). Scale: 0=not noticeable, 1=noticeable but not bothersome, 2=noticeable and bothersome some of the time, 3=bothersome most of the time and/or very bothersome some of the time.
Time Frame	Baseline To 1-2 Weeks
Safety Issue?	No

Analysis Population Description

The Intent-to-Treat (ITT) population, the basis for superiority comparisons between FSC+FPANS and FSC+MON in the context of rhinitis measures, included all subjects randomized to double-blind treatment. Families of secondary efficacy measures were each adjusted for multiplicity using Hochberg's method.

Reporting Groups

	Description
Flut Prop/Salmeterol/Flut Nasal Spray (FSC+FPANS)	
Fluticasone Propionate/Salmeterol/ Montelukast (FSC+MON)	

Measured Values

	Flut Prop/Salmeterol/Flut Nasal Spray (FSC+FPANS)	Fluticasone Propionate/Salmeterol/ Montelukast (FSC+MON)
Number of Participants Analyzed	181	181
Rhinitis: Mean Change From Baseline at 1-2 Weeks in Nightime Total Nasal Symptom Scores (N-TNSS) [units: Points on a Scale] Mean (Standard Error)	-2.0 (0.13)	1.7 (0.13)

5. Secondary Outcome Measure:

Measure Title	Asthma: Mean Change From Baseline at Endpoint in Predose Morning Forced Expiratory Volume (FEV1) for Intent-to-Treat Population
Measure Description	Endpoint was defined as the average of the last week's worth of evaluable data. The volume of air that can be forced out taking a deep breath, an important measure of pulmonary function. FEV1 is forced expiratory volume in one second.
Time Frame	Baseline to Endpoint (weeks 3-4)
Safety Issue?	No

Analysis Population Description

The Intent-to-Treat (ITT) population, the basis for superiority comparisons between FSC and MON in the context of asthma measures, included all subjects randomized to double-blind treatment. Families of secondary efficacy measures were each adjusted for multiplicity using Hochberg's method.

Reporting Groups

	Description
Fluticasone Propionate/Salmeterol (FSC)	
Montelukast (MON)	

Measured Values

	Fluticasone Propionate/Salmeterol (FSC)	Montelukast (MON)
Number of Participants Analyzed	178	180
Asthma: Mean Change From Baseline at Endpoint in Predose Morning Forced Expiratory Volume (FEV1) for Intent-to-Treat Population [units: L/sec] Mean (Standard Error)	0.15 (0.02)	0.04 (0.03)

6. Secondary Outcome Measure:

Measure Title	Asthma: Mean Change From Baseline at Endpoint in Predose Morning Forced Expiratory Volume (FEV1) for Per Protocol Population
Measure Description	Endpoint was defined as the average of the last week's worth of evaluable data. The volume of air that can be forced out taking a deep breath, an important measure of pulmonary function. FEV1 is forced expiratory volume in one second.
Time Frame	Baseline to Endpoint (weeks 3-4)
Safety Issue?	No

Analysis Population Description

The Per Protocol population, the basis for equivalence comparison between FSC and FSC+MON in terms of asthma measures, included subjects from the ITT population who did not deviate significantly from the protocol. Families of secondary efficacy measures were each adjusted for multiplicity using Hochberg's method.

Reporting Groups

	Description
Fluticasone Propionate/Salmeterol/ Montelukast (FSC+MON)	
Fluticasone Propionate/Salmeterol (FSC)	

Measured Values

	Fluticasone Propionate/Salmeterol/ Montelukast (FSC+MON)	Fluticasone Propionate/Salmeterol (FSC)
Number of Participants Analyzed	83	88
Asthma: Mean Change From Baseline at Endpoint in Predose Morning Forced Expiratory Volume (FEV1) for Per Protocol Population [units: L/sec] Mean (Standard Error)	0.27 (0.04)	0.13 (0.04)

7. Secondary Outcome Measure:

Measure Title	Asthma: Mean Change From Baseline at Endpoint in Percentage of Asthma Symptom-Free Days for Intent-to-Treat Population
Measure Description	Endpoint was defined as the average of the data reported from the last week of treatment.Asthma symptom scores and the subject-rated overall satisfaction with treatment, related to the percentage of asthma symptom-free days. Same scale used as in outcome 8.
Time Frame	Baseline to Endpoint (weeks 3-4)
Safety Issue?	No

Analysis Population Description

The Intent-to-Treat (ITT) population, the basis for superiority comparisons between FSC and MON in the context of asthma measures, included all subjects randomized to double-blind treatment. Families of secondary efficacy measures were each adjusted for multiplicity using Hochberg's method.

Reporting Groups

	Description
Fluticasone Propionate/Salmeterol (FSC)	
Montelukast (MON)	

Measured Values

	Fluticasone Propionate/Salmeterol (FSC)	Montelukast (MON)
Number of Participants Analyzed	179	181
Asthma: Mean Change From Baseline at Endpoint in Percentage of Asthma Symptom-Free Days for Intent-to-Treat Population	34.8 (2.94)	26.1 (2.83)

	Fluticasone Propionate/Salmeterol (FSC)	Montelukast (MON)
[units: Percentage of asthma symptom-free days] Mean (Standard Error)		

8. Secondary Outcome Measure:

Measure Title	Asthma: Mean Change From Baseline at Endpoint in Percentage of Asthma Symptom-Free Days for Per Protocol Population
Measure Description	Asthma symptom score:0=no symptoms,1=symptoms 1 short period,2=symptoms 2 or more short periods,3=symptoms most of day not affect activities,4=symptoms most of day did affect activities,5=symptoms severe.Overall satisfaction score:0=very dissatisfied,1=dissatisfied,2=slightly dissatisfied,3=neutral,4=slightly satisfied,5=satisfied 6=very satisfied
Time Frame	Baseline to Endpoint (weeks 3-4)
Safety Issue?	No

Analysis Population Description

The Per Protocol population, the basis for equivalence comparison between FSC and FSC+MON in terms of asthma measures, included subjects from the ITT population who did not deviate significantly from the protocol. Families of secondary efficacy measures were each adjusted for multiplicity using Hochberg's method.

Reporting Groups

	Description
Fluticasone Propionate/Salmeterol/ Montelukast (FSC+MON)	
Fluticasone Propionate/Salmeterol (FSC)	

Measured Values

	Fluticasone Propionate/Salmeterol/ Montelukast (FSC+MON)	Fluticasone Propionate/Salmeterol (FSC)
Number of Participants Analyzed	83	88
Asthma: Mean Change From Baseline at Endpoint in Percentage of Asthma Symptom-Free Days for Per Protocol Population [units: Percentage of asthma symptom-free days] Mean (Standard Error)	34.8 (4.32)	37.1 (4.23)

9. Secondary Outcome Measure:

Measure Title	Asthma: Mean Change From Baseline at Endpoint in Percentage of Albuterol-Salbutamol Free Days for Intent-to-Treat Population
Measure Description	Endpoint was defined as the average of the data reported from the last week of treatment. Albuterol/salbutamol use (related to percentage of asthma rescue-free days).
Time Frame	Baseline to Endpoint (weeks 3-4)
Safety Issue?	No

Analysis Population Description

The Intent-to-Treat (ITT) population, the basis for superiority comparisons between FSC and MON in the context of asthma measures, included all subjects randomized to double-blind treatment. Families of secondary efficacy measures were each adjusted for multiplicity using Hochberg's method.

Reporting Groups

	Description
Fluticasone Propionate/Salmeterol (FSC)	
Montelukast (MON)	

Measured Values

	Fluticasone Propionate/Salmeterol (FSC)	Montelukast (MON)
Number of Participants Analyzed	179	181
Asthma: Mean Change From Baseline at Endpoint in Percentage of Albuterol-Salbutamol Free Days for Intent-to-Treat Population [units: Percentage of rescue-free days] Mean (Standard Error)	37.5 (2.84)	26.7 (2.92)

10. Secondary Outcome Measure:

Measure Title	Asthma: Mean Change From Baseline at Endpoint in Percentage of Albuterol/Salbutamol-Free Days for Per Protocol Population
Measure Description	Endpoint was defined as the average of the data reported from the last week of treatment. Albuterol/salbutamol use (related to percentage of asthma rescue-free days).
Time Frame	Baseline to Endpoint (weeks 3-4)
Safety Issue?	No

Analysis Population Description

The Per Protocol population, the basis for equivalence comparison between FSC and FSC+MON in terms of asthma measures, included subjects from the ITT population who did not deviate significantly from the protocol. Families of secondary efficacy measures were each adjusted for multiplicity using Hochberg's method.

Reporting Groups

	Description
Fluticasone Propionate + Salmeterol & Montelukast (FSC+MON)	
Fluticasone Propionate/Salmeterol (FSC)	

Measured Values

	Fluticasone Propionate + Salmeterol & Montelukast (FSC+MON)	Fluticasone Propionate/Salmeterol (FSC)
Number of Participants Analyzed	83	88
Asthma: Mean Change From Baseline at Endpoint in Percentage of Albuterol/Salbutamol-Free Days for Per Protocol Population [units: Percentage of rescue-free days] Mean (Standard Error)	41.2 (3.97)	42.9 (4.20)

Reported Adverse Events

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

Reporting Groups

	Description
Fluticasone Prop/Salmeterol/Flut Prop Nasal Spray (FSC+FPANS)	Fluticasone Prop/Salmeterol/Flut Prop Nasal Spray (FSC+FPANS) = FSC twice a day (BID), plus FPANS (once a day) QD, plus placebo capsule once a day (QD).
Fluticasone Propionate/Salmeterol/ Montelukast (FSC+MON)	Fluticasone Propionate/Salmeterol/Montelukast (FSC+MON) = FSC twice a day (BID), plus vehicle placebo nasal spray once a day (QD), plus MON once a day (QD)

	Description
Fluticasone Propionate/Salmeterol (FSC)	Fluticasone Propionate/Salmeterol (FSC) = FSC BID, plus vehicle placebo nasal spray once a day (QD), plus placebo capsule once a day (QD).
Montelukast (MON)	Montelukast (MON) = Placebo DISKUS BID, plus vehicle placebo nasal spray once a day (QD), plus MON (once a day) QD.

Serious Adverse Events

	Fluticasone Prop/ Salmeterol/Flut Prop Nasal Spray (FSC+FPANS)	Fluticasone Propionate/ Salmeterol/Montelukast (FSC+MON)	Fluticasone Propionate/ Salmeterol (FSC)	Montelukast (MON)
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	0/182 (0%)	1/182 (0.55%)	1/180 (0.56%)	1/181 (0.55%)
Gastrointestinal disorders				
Gastrooesophageal reflux disease [A]	0/182 (0%)	0/182 (0%)	1/180 (0.56%)	0/181 (0%)
Infections and infestations				
Appendicitis [A]	0/182 (0%)	0/182 (0%)	0/180 (0%)	1/181 (0.55%)
Injury, poisoning and procedural complications				
Spinal fracture [A]	0/182 (0%)	1/182 (0.55%)	0/180 (0%)	0/181 (0%)

A Term from vocabulary, MedDRA

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 0%

	Fluticasone Prop/ Salmeterol/Flut Prop Nasal Spray (FSC+FPANS)	Fluticasone Propionate/ Salmeterol/Montelukast (FSC+MON)	Fluticasone Propionate/ Salmeterol (FSC)	Montelukast (MON)
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	32/182 (17.58%)	32/182 (17.58%)	42/180 (23.33%)	41/181 (22.65%)
Ear and labyrinth disorders				
Ear disorder [A]	0/182 (0%)	1/182 (0.55%)	0/180 (0%)	0/181 (0%)
Ear pain [A]	0/182 (0%)	0/182 (0%)	0/180 (0%)	1/181 (0.55%)

	Fluticasone Prop/ Salmeterol/Flut Prop Nasal Spray (FSC+FPANS)	Fluticasone Propionate/ Salmeterol/Montelukast (FSC+MON)	Fluticasone Propionate/ Salmeterol (FSC)	Montelukast (MON)
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Eye disorders				
Conjunctivitis [A]	0/182 (0%)	0/182 (0%)	1/180 (0.56%)	1/181 (0.55%)
Dry eye [A]	0/182 (0%)	1/182 (0.55%)	0/180 (0%)	0/181 (0%)
Eye pruritis [A]	2/182 (1.1%)	0/182 (0%)	0/180 (0%)	0/181 (0%)
Eye swelling [A]	1/182 (0.55%)	0/182 (0%)	0/180 (0%)	0/181 (0%)
Gastrointestinal disorders				
Abdominal pain upper [A]	0/182 (0%)	0/182 (0%)	1/180 (0.56%)	2/181 (1.1%)
Aphthous stomatitis [A]	0/182 (0%)	0/182 (0%)	0/180 (0%)	1/181 (0.55%)
Diarrhoea [A]	2/182 (1.1%)	0/182 (0%)	0/180 (0%)	3/181 (1.66%)
Dyspepsia [A]	0/182 (0%)	1/182 (0.55%)	0/180 (0%)	0/181 (0%)
Food poisoning [A]	1/182 (0.55%)	0/182 (0%)	0/180 (0%)	1/181 (0.55%)
Nausea [A]	2/182 (1.1%)	1/182 (0.55%)	0/180 (0%)	1/181 (0.55%)
Oral pain [A]	0/182 (0%)	0/182 (0%)	1/180 (0.56%)	1/181 (0.55%)
Stomach discomfort [A]	0/182 (0%)	0/182 (0%)	0/180 (0%)	1/181 (0.55%)
Vomiting [A]	0/182 (0%)	0/182 (0%)	0/180 (0%)	3/181 (1.66%)
General disorders				
Chest pain [A]	0/182 (0%)	1/182 (0.55%)	1/180 (0.56%)	0/181 (0%)
Injection site pain [A]	0/182 (0%)	0/182 (0%)	1/180 (0.56%)	0/181 (0%)
Oedema peripheral [A]	1/182 (0.55%)	0/182 (0%)	0/180 (0%)	0/181 (0%)
Pyrexia [A]	0/182 (0%)	0/182 (0%)	1/180 (0.56%)	2/181 (1.1%)
Hepatobiliary disorders				

	Fluticasone Prop/ Salmeterol/Flut Prop Nasal Spray (FSC+FPANS)	Fluticasone Propionate/ Salmeterol/Montelukast (FSC+MON)	Fluticasone Propionate/ Salmeterol (FSC)	Montelukast (MON)
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Cholelithiasis [A]	0/182 (0%)	0/182 (0%)	0/180 (0%)	1/181 (0.55%)
Immune system disorders				
Anaphylactic reaction [A]	0/182 (0%)	0/182 (0%)	1/180 (0.56%)	0/181 (0%)
Food allergy [A]	0/182 (0%)	1/182 (0.55%)	0/180 (0%)	0/181 (0%)
Hypersensitivity [A]	1/182 (0.55%)	0/182 (0%)	0/180 (0%)	0/181 (0%)
Infections and infestations				
Acute sinusitis [A]	0/182 (0%)	0/182 (0%)	0/180 (0%)	1/181 (0.55%)
Appendicitis [A]	0/182 (0%)	0/182 (0%)	0/180 (0%)	1/181 (0.55%)
Bronchitis [A]	1/182 (0.55%)	0/182 (0%)	0/180 (0%)	0/181 (0%)
Clostridial infection [A]	0/182 (0%)	0/182 (0%)	0/180 (0%)	1/181 (0.55%)
Cystitis [A]	0/182 (0%)	0/182 (0%)	1/180 (0.56%)	0/181 (0%)
Eye infection [A]	0/182 (0%)	0/182 (0%)	0/180 (0%)	1/181 (0.55%)
Gastroenteritis [A]	2/182 (1.1%)	0/182 (0%)	0/180 (0%)	0/181 (0%)
Gastroenteritis viral [A]	0/182 (0%)	1/182 (0.55%)	1/180 (0.56%)	1/181 (0.55%)
Influenza [A]	0/182 (0%)	1/182 (0.55%)	0/180 (0%)	1/181 (0.55%)
Laryngitis [A]	0/182 (0%)	1/182 (0.55%)	0/180 (0%)	0/181 (0%)
Lower respiratory tract infection [A]	0/182 (0%)	2/182 (1.1%)	0/180 (0%)	0/181 (0%)
Nasopharyngitis [A]	1/182 (0.55%)	3/182 (1.65%)	4/180 (2.22%)	0/181 (0%)
Oral candidiasis [A]	0/182 (0%)	1/182 (0.55%)	2/180 (1.11%)	0/181 (0%)
Oral herpes [A]	0/182 (0%)	0/182 (0%)	1/180 (0.56%)	0/181 (0%)
Otitis media [A]	0/182 (0%)	0/182 (0%)	0/180 (0%)	1/181 (0.55%)

	Fluticasone Prop/ Salmeterol/Flut Prop Nasal Spray (FSC+FPANS)	Fluticasone Propionate/ Salmeterol/Montelukast (FSC+MON)	Fluticasone Propionate/ Salmeterol (FSC)	Montelukast (MON)
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Pharyngitis streptococcal [A]	0/182 (0%)	0/182 (0%)	0/180 (0%)	1/181 (0.55%)
Respiratory tract infection viral [A]	0/182 (0%)	0/182 (0%)	0/180 (0%)	1/181 (0.55%)
Sinusitis [A]	3/182 (1.65%)	0/182 (0%)	4/180 (2.22%)	1/181 (0.55%)
Tooth abscess [A]	0/182 (0%)	0/182 (0%)	0/180 (0%)	1/181 (0.55%)
Upper respiratory tract infection [A]	1/182 (0.55%)	1/182 (0.55%)	3/180 (1.67%)	4/181 (2.21%)
Urinary tract infection [A]	0/182 (0%)	1/182 (0.55%)	0/180 (0%)	0/181 (0%)
Viral infection [A]	0/182 (0%)	0/182 (0%)	1/180 (0.56%)	0/181 (0%)
Viral upper respiratory tract infection [A]	0/182 (0%)	0/182 (0%)	0/180 (0%)	1/181 (0.55%)
Injury, poisoning and procedural complications				
Arthropod sting [A]	1/182 (0.55%)	0/182 (0%)	0/180 (0%)	0/181 (0%)
Joint injury [A]	1/182 (0.55%)	0/182 (0%)	0/180 (0%)	0/181 (0%)
Joint sprain [A]	0/182 (0%)	1/182 (0.55%)	0/180 (0%)	0/181 (0%)
Meniscus lesion [A]	0/182 (0%)	0/182 (0%)	1/180 (0.56%)	1/181 (0.55%)
Muscle strain [A]	0/182 (0%)	0/182 (0%)	0/180 (0%)	0/181 (0%)
Neck injury [A]	0/182 (0%)	1/182 (0.55%)	0/180 (0%)	0/181 (0%)
Procedural pain [A]	0/182 (0%)	1/182 (0.55%)	0/180 (0%)	0/181 (0%)
Road traffic accident [A]	1/182 (0.55%)	0/182 (0%)	0/180 (0%)	0/181 (0%)
Skin laceration [A]	0/182 (0%)	1/182 (0.55%)	0/180 (0%)	0/181 (0%)
Tooth fracture [A]	1/182 (0.55%)	0/182 (0%)	0/180 (0%)	0/181 (0%)
Investigations				
Weight increased [A]	0/182 (0%)	1/182 (0.55%)	0/180 (0%)	0/181 (0%)

	Fluticasone Prop/ Salmeterol/Flut Prop Nasal Spray (FSC+FPANS)	Fluticasone Propionate/ Salmeterol/Montelukast (FSC+MON)	Fluticasone Propionate/ Salmeterol (FSC)	Montelukast (MON)
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Musculoskeletal and connective tissue disorders				
Arthralgia [A]	0/182 (0%)	0/182 (0%)	1/180 (0.56%)	1/181 (0.55%)
Arthritis [A]	1/182 (0.55%)	0/182 (0%)	0/180 (0%)	0/181 (0%)
Back pain [A]	2/182 (1.1%)	1/182 (0.55%)	3/180 (1.67%)	1/181 (0.55%)
Bursitis [A]	1/182 (0.55%)	0/182 (0%)	0/180 (0%)	0/181 (0%)
Muscle spasms [A]	1/182 (0.55%)	1/182 (0.55%)	1/180 (0.56%)	1/181 (0.55%)
Muscle twitching [A]	0/182 (0%)	0/182 (0%)	0/180 (0%)	1/181 (0.55%)
Musculoskeletal pain [A]	0/182 (0%)	1/182 (0.55%)	1/180 (0.56%)	0/181 (0%)
Musculoskeletal stiffness [A]	2/182 (1.1%)	0/182 (0%)	0/180 (0%)	0/181 (0%)
Myalgia [A]	1/182 (0.55%)	2/182 (1.1%)	1/180 (0.56%)	1/181 (0.55%)
Pain in extremity [A]	1/182 (0.55%)	0/182 (0%)	0/180 (0%)	0/181 (0%)
Tendonitis [A]	0/182 (0%)	0/182 (0%)	0/180 (0%)	1/181 (0.55%)
Nervous system disorders				
Dizziness [A]	0/182 (0%)	1/182 (0.55%)	0/180 (0%)	0/181 (0%)
Headache [A]	7/182 (3.85%)	7/182 (3.85%)	8/180 (4.44%)	8/181 (4.42%)
Migraine [A]	1/182 (0.55%)	1/182 (0.55%)	1/180 (0.56%)	0/181 (0%)
Sinus headache [A]	0/182 (0%)	2/182 (1.1%)	3/180 (1.67%)	1/181 (0.55%)
Tremor [A]	1/182 (0.55%)	0/182 (0%)	0/180 (0%)	0/181 (0%)
Psychiatric disorders				
Anorgasmia [A]	0/182 (0%)	0/182 (0%)	0/180 (0%)	1/181 (0.55%)
Insomnia [A]	0/182 (0%)	0/182 (0%)	0/180 (0%)	1/181 (0.55%)

	Fluticasone Prop/ Salmeterol/Flut Prop Nasal Spray (FSC+FPANS)	Fluticasone Propionate/ Salmeterol/Montelukast (FSC+MON)	Fluticasone Propionate/ Salmeterol (FSC)	Montelukast (MON)
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Middle insomnia [A]	0/182 (0%)	0/182 (0%)	1/180 (0.56%)	0/181 (0%)
Reproductive system and breast disorders				
Dysmenorrhoea [A]	0/182 (0%)	1/182 (0.55%)	1/180 (0.56%)	3/181 (1.66%)
Menorrhagia [A]	0/182 (0%)	1/182 (0.55%)	0/180 (0%)	0/181 (0%)
Metrorrhagia [A]	0/182 (0%)	0/182 (0%)	0/180 (0%)	1/181 (0.55%)
Ovarian cyst [A]	0/182 (0%)	0/182 (0%)	1/180 (0.56%)	0/181 (0%)
Respiratory, thoracic and mediastinal disorders				
Cough [A]	1/182 (0.55%)	0/182 (0%)	1/180 (0.56%)	0/181 (0%)
Dry throat [A]	0/182 (0%)	0/182 (0%)	0/180 (0%)	1/181 (0.55%)
Epistaxis [A]	0/182 (0%)	1/182 (0.55%)	4/180 (2.22%)	3/181 (1.66%)
Nasal congestion [A]	0/182 (0%)	0/182 (0%)	1/180 (0.56%)	1/181 (0.55%)
Nasal discomfort [A]	0/182 (0%)	1/182 (0.55%)	1/180 (0.56%)	0/181 (0%)
Nasal dryness [A]	0/182 (0%)	0/182 (0%)	0/180 (0%)	1/181 (0.55%)
Nasal polyps [A]	0/182 (0%)	0/182 (0%)	0/180 (0%)	1/181 (0.55%)
Pharyngolaryngeal pain [A]	1/182 (0.55%)	1/182 (0.55%)	2/180 (1.11%)	4/181 (2.21%)
Respiratory tract congestion [A]	0/182 (0%)	0/182 (0%)	1/180 (0.56%)	1/181 (0.55%)
Rhinitis allergic [A]	0/182 (0%)	0/182 (0%)	0/180 (0%)	1/181 (0.55%)
Rhinitis perennial [A]	0/182 (0%)	0/182 (0%)	0/180 (0%)	1/181 (0.55%)
Rhinorrhoea [A]	0/182 (0%)	0/182 (0%)	1/180 (0.56%)	0/181 (0%)
Sinus congestion [A]	0/182 (0%)	0/182 (0%)	1/180 (0.56%)	0/181 (0%)
Throat irritation [A]	0/182 (0%)	0/182 (0%)	0/180 (0%)	1/181 (0.55%)

	Fluticasone Prop/ Salmeterol/Flut Prop Nasal Spray (FSC+FPANS)	Fluticasone Propionate/ Salmeterol/Montelukast (FSC+MON)	Fluticasone Propionate/ Salmeterol (FSC)	Montelukast (MON)
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Skin and subcutaneous tissue disorders				
Dermatitis contact [A]	1/182 (0.55%)	0/182 (0%)	0/180 (0%)	0/181 (0%)
Petechiae [A]	0/182 (0%)	1/182 (0.55%)	0/180 (0%)	0/181 (0%)
Rash [A]	0/182 (0%)	1/182 (0.55%)	0/180 (0%)	1/181 (0.55%)
Surgical and medical procedures				
Shoulder operation [A]	1/182 (0.55%)	0/182 (0%)	0/180 (0%)	0/181 (0%)
Vascular disorders				
Haematoma [A]	0/182 (0%)	1/182 (0.55%)	0/180 (0%)	0/181 (0%)

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 centres of a multi-centre trial but requests that reports based on single-site data not precede the primary publication of the entire clinical trial.

Results Point of Contact:

Name/Official Title: GSK Response Center
Organization: GlaxoSmithKline
Phone: 866-435-7343

Email: