ClinicalTrials.gov Protocol and Results Registration System (PRS) Receipt
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Safety Study of the Effects of Inhaled Fluticasone Furoate/GW642444 on the Hypothalamic-Pituitary-Adrenal (HPA) Axis

This study has been completed.

Sponsor:	GlaxoSmithKline
Collaborators:	
Information provided by (Responsible Party):	GlaxoSmithKline
ClinicalTrials.gov Identifier:	NCT01086410

Purpose

The purpose of this study is to assess the effect of six weeks' treatment with two once-daily strengths of Fluticasone Furoate/GW642444 Inhalation Powder on the HPA axis system

Condition	Intervention	Phase
Asthma	Drug: Placebo Inhalation Powder Drug: Fluticasone Furoate/GW642444 Inhalation Powder Drug: Placebo Oral Capsule Drug: Prednisolone Oral Capsule	Phase 3

Study Type: Interventional

Study Design: Treatment, Parallel Assignment, Double Blind (Subject, Investigator), Randomized, Safety Study

Official Title: Study HZA106851: A Study of the Effects of Inhaled Fluticasone Furoate/GW642444 Versus Placebo on the HPA Axis of Adolescent and Adult Asthmatics

Further study details as provided by GlaxoSmithKline:

Primary Outcome Measure:

- Ratio From Baseline of the Serum Cortisol Weighted Mean (0-24 Hours) on Day -1/1 (Baseline) and Day 42 [Time Frame: Day -1/1 (Baseline) and Day 42] [Designated as safety issue: No]

  Serum cortisol weighted mean was determined for each participant over the time period 0-12 hours on Day -1/1 (Baseline) and Day 42. Serum cortisol weighted mean was derived by dividing the area under the concentration-time curve (AUC; defined as thearea under the concentration-time curve from time zero up to 24 hours) by the sample collection time interval. The sample collection time interval is defined as the difference between the time of the last cortisol sample and the time of the first cortisol sample. Samples were collected at the following time points: 0 (first blood draw/pre-dose); 2, 4, 9, 12, 14, 16, 20, 22, and 24 hours (relative to the "0" time point). Because values are on a logged scale, the ratio of the endpoint to Baseline is presented, as it is a measure of the difference from Baseline.

Secondary Outcome Measures:

- Ratio From Baseline of the Serum Cortisol Area Under the Concentration-time Curve (AUC) (0-24 Hour) on Day -1/1 (Baseline) and Day 42 [Time Frame: Day -1/1 (Baseline) and Day 42] [Designated as safety issue: No]

  Area under the plasma drug concentration-time (AUC[0-24 hour]) curve from time zero (pre-dose) to the last time of quantifiable serum cortisol concentration at 24 hours post-dose on Day -1/1 (Baseline) and Day 42 was measured. AUC reflects the actual body exposure to drug over a specified period of time after administration of a dose. Samples were collected at the following times: 0 (immediately pre-dose inhaled study drug); post-dose at 5 minutes (min), 15 min, 30 min, and 1 hour (hr), 2 hr, 4 hr, 9 hr, 12 hr, 16 hr, 20 hr, and 24 hr. Because values are on a logged scale, the ratio of the endpoint to Baseline is presented, as it is a measure of the difference from Baseline.
- Ratio From Baseline of Serum Cortisol Trough (0-24 Hours) at Day -1/1 (Baseline) and Day 42 [Time Frame: Day -1/1 (Baseline) and Day 42] [Designated as safety issue: No]

  Serum cortisol trough is defined as the minimum value of serum cortisol measured over the 24-hour period. Samples were collected at the following times: 0 (immediately pre-dose inhaled study drug); post-dose at 5 minutes (min), 15 min, 30 min, and 1 hour (hr), 2 hr, 4 hr, 9 hr, 12 hr, 16 hr, 20 hr, and 24 hr. Because values are on a logged scale, the ratio of the endpoint to Baseline is presented, as it is a measure of the difference from Baseline.
- Ratio From Baseline of 0-24 Hour Urinary Free Cortisol Excretion on Day -1/1 (Baseline) and Day 42 [Time Frame: Day -1/1 (Baseline) and Day 42] [Designated as safety issue: No]

  A 24-hour urine sample was collected for the measurement of 24-hour urinary cortisol excretion at Day -1/1 (Baseline) and Day 42. Only those participants available at the specified time points were analyzed. Because values are on a logged scale, the ratio of the endpoint to Baseline is presented, as it is a measure of the difference from Baseline.
- Plasma FF and VI Pharmacokinetic (PK) Concentration [Time Frame: Day 42] [Designated as safety issue: No]

  Plasma FF and VI Pharmacokinetic (PK) Concentration were estimates at the following time points:0 (immediately pre-dose inhaled study drug), and

post-dose at 5 min, 15 min, 30 min, and 1 hr, 2 hr, 4 hr, 9 hr, 12 hr, 16 hr, 20 hr, 24 hr on Day 42. Only those participants available at the specified time points were analyzed (represented by n=X, X, X, X in the category titles). Different participants may have been analyzed at different time points, so the overall number of participants analyzed reflects everyone in the Pharmacokinetic Population.

- AUC(0-t) and AUC(0-24) for FF on Day 42 [Time Frame: Day 42] [Designated as safety issue: No]
  Area under the plasma drug concentration-time (AUC[0-t]) curve from time zero (pre-dose) to the last time of quantifiable FF concentration and AUC(0-24) is the concentration time curve from zero (pre-dose) to 24 hours of quantifiable FF concentration on Day 42 was measured. AUC reflects the actual body exposure to drug over a specified period of time after administration of a dose. Samples were collected at the following times: 0 (immediately pre-dose inhaled study drug); post-dose at 5 minutes (min), 15 min, 30 min, and 1 hour (hr), 2 hr, 4 hr, 9 hr, 12 hr, 16 hr, 20 hr, and 24 hr post-dose on Day 42.
- Cmax for FF on Day 42 [Time Frame: Day 42] [Designated as safety issue: No]
  Cmax is defined as the maximum observed concentration on Day 42. Samples were collected at the following times: 0 (immediately pre-dose inhaled study drug); post-dose at 5 minutes (min), 15 min, 30 min, and 1 hour (hr), 2 hr, 4 hr, 9 hr, 12 hr, 16 hr, 20 hr, and 24 hr post-dose on Day 42.
- Tmax and Tlast of FF at Day 42 [Time Frame: Day 42] [Designated as safety issue: No]
  tmax is defined as the time to reach the observed maximum concentration, and tlast is defined as the time of the last observed quantifiable concentration on Day 42. Samples were collected at the following times: 0 (immediately pre-dose inhaled study drug); post-dose at 5 minutes (min), 15 min, 30 min, and 1hour (hr), 2 hr, 4 hr, 9 hr, 12 hr, 16 hr, 20 hr, and 24 hr post-dose on Day 42.
- AUC(0-t) for VI on Day 42 [Time Frame: Day 42] [Designated as safety issue: No]
  Area under the concentration-time (AUC[0-t]) curve from time zero (pre-dose) to the last time of quantifiable VI concentration on Day 42 was measured. Samples were collected at the following times: 0 (immediately pre-dose inhaled study drug); post-dose at 5 minutes (min), 15 min, 30 min, and 1 hour (hr), 2 hr, 4 hr, 9 hr, 12 hr, 16 hr, 20 hr, and 24 hr post-dose on Day 42.
- Cmax for VI on Day 42 [Time Frame: Day 42] [Designated as safety issue: No]
  Cmax is defined as the maximum observed concentration on Day 42. Samples were collected at the following times: 0 (immediately pre-dose inhaled study drug); post-dose at 5 minutes (min), 15 min, 30 min, and 1 hour (hr), 2 hr, 4 hr, 9 hr, 12 hr, 16 hr, 20 hr, and 24 hr post-dose on Day 42.
- Tmax and Tlast of VI at Day 42 [Time Frame: Day 42] [Designated as safety issue: No]
  tmax is defined as the time to reach the observed maximum concentration, and tlast is defined as the time of the last observed quantifiable VI concentration on Day 42. Samples were collected at the following times: 0 (immediately pre-dose inhaled study drug); post-dose at 5 minutes (min), 15 min, 30 min, and 1hour (hr), 2 hr, 4 hr, 9 hr, 12 hr, 16 hr, 20 hr, and 24 hr post-dose on Day 42.
- Number of Participants With Any Adverse Event (AE) or Any Serious Adverse Event (SAE) During the Treatment Period [Time Frame: From the start of study medication until Day 42 (Visit 5)/Early Withdrawal] [Designated as safety issue: No]
  An AE is defined as any untoward medical occurrence in a participant or clinical investigation participant, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. A serious adverse event (SAE) is defined as any untoward medical occurrence that, at any dose, results in death, is life threatening, requires hospitalization or prolongation of existing hospitalization, results in disability/incapacity, or is a congenital anomaly/birth defect. Medical or scientific judgment should be exercised in deciding whether reporting is appropriate in other situations. Refer to the General Adverse AE/SAE module for a complete list of AEs and SAEs.
- Change From Baseline in Basophil, Eosinophil, Lymphocyte, Monocyte, and Segmented Neutrophil Values at Day 42/Early Withdrawal (EW) [Time Frame:

Baseline and Day 42/Early Withdrawal (EW)] [Designated as safety issue: No]

Blood samples were collected for the measurement of basophils, eosinophils, lymphocytes, monocytes, and segmented neutrophils at Baseline and Day 42/EW. For all laboratory assessments, Baseline is the most recent recorded value at Screening or prior to Day -1/1. Change from Baseline was calculated as the Day 42/EW value minus the Baseline value.

- Change From Baseline in Eosinophil, Total Neutrophil, Platelet, and White Blood Cell (WBC) Count Values at Day 42/EW [Time Frame: Baseline and Day 42/EW] [Designated as safety issue: No]

  Blood samples were collected for the measurement of eosinophils, total neutrophils, platelets, and WBC count at Baseline and Day 42/EW. For all laboratory assessments, Baseline is the most recent recorded value at Screening or prior to Day -1/1. Change from Baseline was calculated as the Day 42/EW value minus the Baseline value.
- Change From Baseline in Hemoglobin Values at Day 42/EW [Time Frame: Baseline and Day 42/EW] [Designated as safety issue: No]

  Blood samples were collected for the measurement of hemoglobin at Baseline and Day 42/EW. For all laboratory assessments, Baseline is the most recent recorded value at Screening or prior to Day -1/1. Change from Baseline was calculated as the Day 42/EW value minus the Baseline value.
- Change From Baseline in Hematocrit Values at Day 42/EW [Time Frame: Baseline and Day 42/EW] [Designated as safety issue: No]

  Blood samples were collected for the measurement of hematocrit at Baseline and Day 42/EW. For all laboratory assessments, Baseline is the most recent recorded value at Screening or prior to Day -1/1. Change from Baseline was calculated as the Day 42/EW value minus the Baseline value.
- Change From Baseline in Alanine Amino Transferase (ALT), Alkaline Phosphatase (ALP), Aspartate Amino Transferase (AST), Creatine Kinase (CK), and Gamma Glutamyl Transferase (GGT) Values at Day 42/EW [Time Frame: Baseline and Day 42/EW] [Designated as safety issue: No]

  Blood samples were collected for the measurement of ALT, ALP, AST, CK, and GGT at Baseline and Day 42/EW. For all laboratory assessments, Baseline is the most recent recorded value at Screening or prior to Day -1/1. Change from Baseline was calculated as the Day 42/EW value minus the Baseline value.
- Change From Baseline in Albumin and Total Protein Values at Day 42/EW [Time Frame: Baseline and Day 42/EW] [Designated as safety issue: No]

  Blood samples were collected for the measurement of albumin and total protein at Baseline and Day 42/EW. For all laboratory assessments, Baseline is the most recent recorded value at Screening or prior to Day -1/1. Change from Baseline was calculated as the Day 42/EW value minus the Baseline value.
- Change From Baseline in Direct Bilirubin, Indirect Bilirubin, Total Bilirubin, and Creatinine Values at Day 42/EW [Time Frame: Baseline and Day 42/EW] [Designated as safety issue: No]

  Blood samples were collected for the measurement of direct bilirubin, indirect bilirubin, total bilirubin, and creatinine at Baseline and Day 42/EW. For all laboratory assessments, Baseline is the most recent recorded value at Screening or prior to Day -1/1. Change from Baseline was calculated as the Day 42/EW value minus the Baseline value.
- Change From Baseline in Chloride, Carbon Dioxide (CO2) Content/Bicarbonate, Glucose, Potassium, Sodium, and Urea/Blood Urea Nitrogen (BUN) Values at Day 42/EW [Time Frame: Baseline and Day 42/EW] [Designated as safety issue: No]

  Blood samples were collected for the measurement of chloride, carbon dioxide (CO2) content/bicarbonate, glucose, potassium, sodium, and urea/blood urea nitrogen (BUN) at Baseline and Day 42/EW. For all laboratory assessments, Baseline is the most recent recorded value at Screening or prior to Day -1/1. Change from Baseline was calculated as the Day 42/EW value minus the Baseline value.
- Change From Baseline in Systolic Blood Pressure (SBP) and Diastolic Blood Pressure (DBP) at Days 14, 28, 42, and Maximum Post-Baseline [Time

Frame: Days 14, 28, 42, and EW] [Designated as safety issue: No]

SBP and DBP were measured at Baseline and at Days 14, 28, 42, and EW. Change from Baseline was calculated as the Day 42/EW value minus the Baseline value. Scheduled, unscheduled, and early withdrawal visits were used for the maximum post-Baseline assessment.

- Change From Baseline in Pulse Rate at Days 14, 28, 42, and Maximum Post-Baseline [Time Frame: Days 14, 28, 42, and EW] [Designated as safety issue: No]

  Heart rate was measured at Baseline and at Days 14, 28, 42, and EW. Change from Baseline was calculated as the Day 42/EW value minus the Baseline value. Scheduled, unscheduled, and early withdrawal visits were used for the maximum post-Baseline assessment.

Enrollment: 185
Study Start Date: March 2010
Primary Completion Date: September 2010
Study Completion Date: September 2010

Arms	Assigned Interventions
Active Comparator: FF/444 Dose B Fluticasone furoate/GW642444 Dose B inhalation powder once daily for 6 weeks' treatment + 1 oral placebo capsule each day on the last 7 days of the study	Drug: Fluticasone Furoate/GW642444 Inhalation Powder Dose B inhaled once daily for 6 weeks' treatment Drug: Placebo Oral Capsule One placebo capsule taken each day on the last 7 days of the study
Active Comparator: FF/444 Dose A Fluticasone furoate/GW642444 Dose A inhalation powder once daily for 6 weeks' treatment + 1 oral placebo capsule each day on the last 7 days of the study	Drug: Fluticasone Furoate/GW642444 Inhalation Powder Dose A inhaled once daily for 6 weeks' treatment Drug: Placebo Oral Capsule One placebo capsule taken each day on the last 7 days of the study
Placebo Comparator: Placebo Placebo inhalation powder once daily for 6 weeks' treatment + 1 oral placebo capsule each day on the last 7 days of the study	Drug: Placebo Inhalation Powder Placebo Inhalation powder inhaled once daily for 6 weeks' treatment Drug: Placebo Oral Capsule One placebo capsule taken each day on the last 7 days of the study

Arms	Assigned Interventions
Active Comparator: Prednisolone Placebo inhalation powder once daily for 6 weeks' treatment + 1 oral prednisolone 10mg capsule each day on the last 7 days of the study	Drug: Placebo Inhalation Powder Placebo Inhalation powder inhaled once daily for 6 weeks' treatment Drug: Prednisolone Oral Capsule Prednisolone 10mg oral capsule taken each day on the last 7 days of the study

Eligibility

Ages Eligible for Study: 12 Years to 65 Years
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Outpatient with ability to comply with study requirements and complete two 24-hour clinic visits
- Clinical diagnosis of asthma for greater than/equal to 12 weeks
- Reversibility FEV1 of at least twelve percent and two hundred milliliters
- FEV1 greater than or equal to fifty percent of predicted

Exclusion Criteria:

- History of life threatening asthma
- Respiratory infection or oral candidiasis
- Asthma exacerbation
- Uncontrolled disease or clinical abnormality
- Allergies to study drugs, study drugs' excipients, medications related to study drugs
- Taking another investigational medication or prohibited medication

Contacts and Locations

Locations

United States, California

GSK Investigational Site

Cypress, California, United States, 90630

GSK Investigational Site

Huntington Beach, California, United States, 92647

United States, Oklahoma

GSK Investigational Site

Oklahoma City, Oklahoma, United States, 73103

United States, Texas

GSK Investigational Site

San Antonio, Texas, United States, 78229

Germany

GSK Investigational Site

Berlin, Berlin, Germany, 10117

GSK Investigational Site

Berlin, Berlin, Germany, 10787

GSK Investigational Site

Hamburg, Hamburg, Germany, 20253

GSK Investigational Site

Frankfurt, Hessen, Germany, 60596

GSK Investigational Site

Magdeburg, Sachsen-Anhalt, Germany, 39112

GSK Investigational Site

Grosshansdorf, Schleswig-Holstein, Germany, 22927

Poland

GSK Investigational Site

Bialystok, Poland, 15-010

GSK Investigational Site

Gdansk, Poland, 80-405

GSK Investigational Site

Gidle, Poland, 97-540

GSK Investigational Site

Krakow, Poland, 31-023

GSK Investigational Site
Lodz, Poland, 93-513
GSK Investigational Site
Olsztyn, Poland, 10-357
GSK Investigational Site
Warszawa, Poland, 01-138

Investigators

Study Director:	GSK Clinical Trials	GlaxoSmithKline

More Information

Responsible Party:	GlaxoSmithKline
Study ID Numbers:	106851
Health Authority:	Poland: Centralna Ewidencja Badań Klinicznych Urząd Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych United States: Institutional Review Board Germany: Federal Institute for Drugs and Medical Devices United States: Food and Drug Administration

Participant Flow

Recruitment Details

Participants who met all the inclusion criteria entered a 7- to 14-day Run-in Period (screening visit [Visit 1]). Participants were provided with albuterol/salbutamol inhalation aerosol for relief of asthma symptoms during the study.

Pre-Assignment Details

At the end of the Run-in Period, participants who meet the randomization criteria were admitted to the clinic in the evening (Visit 2) for the Baseline collection of 24-hour serial serum cortisol samples and urine. Eligible participants were randomly assigned to one of four treatment groups in a 4:4:4:1 ratio.

Reporting Groups

	Description
Placebo	Participants received placebo via a Dry Powder Inhaler (DPI) for 6 weeks, plus a placebo capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation from the DPI once daily at approximately the same time each evening for 6 weeks and to take one placebo capsule each morning on the last 7 days of treatment.
FF/VI 100/25 µg PM	Participants received Fluticasone Furoate/Vilanterol (FF/VI) 100/25 micrograms (µg) via a DPI for 6 weeks, plus a placebo capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation from the DPI once daily at approximately the same time each evening (PM) for 6 weeks and to take one placebo capsule each morning (AM) on the last 7 days of treatment.
FF/VI 200/25 µg PM	Participants received FF/VI 200/25 µg via a DPI for 6 weeks, plus a placebo capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation from the DPI once daily at approximately the same time each evening (PM) for 6 weeks and to take one placebo capsule each morning (AM) on the last 7 days of treatment.
Prednisolone 10 mg AM	Participants received placebo via a DPI for 6 weeks, plus a prednisolone 10 milligram (mg) capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation of placebo from the DPI once daily at approximately the same time each evening (PM) for 6 weeks and to take one Prednisolone capsule each morning (AM) on the last 7 days of treatment.

Overall Study

	Placebo	FF/VI 100/25 µg PM	FF/VI 200/25 µg PM	Prednisolone 10 mg AM
Started	58	56	56	15
Completed	55	54	55	13
Not Completed	3	2	1	2
Adverse Event	1	0	0	2
Lack of Efficacy	1	1	0	0
Protocol Violation	1	1	0	0
Lost to Follow-up	0	0	1	0

Baseline Characteristics

Reporting Groups

	Description
Placebo	Participants received placebo via a Dry Powder Inhaler (DPI) for 6 weeks, plus a placebo capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation from the DPI once daily at approximately the same time each evening for 6 weeks and to take one placebo capsule each morning on the last 7 days of treatment.
FF/VI 100/25 µg PM	Participants received Fluticasone Furoate/Vilanterol (FF/VI) 100/25 micrograms (µg) via a DPI for 6 weeks, plus a placebo capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation from the DPI once daily at approximately the same time each evening (PM) for 6 weeks and to take one placebo capsule each morning (AM) on the last 7 days of treatment.
FF/VI 200/25 µg PM	Participants received FF/VI 200/25 µg via a DPI for 6 weeks, plus a placebo capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation from the DPI once daily at approximately the same time each evening (PM) for 6 weeks and to take one placebo capsule each morning (AM) on the last 7 days of treatment.

	Description
Prednisolone 10 mg AM	Participants received placebo via a DPI for 6 weeks, plus a prednisolone 10 milligram (mg) capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation of placebo from the DPI once daily at approximately the same time each evening (PM) for 6 weeks and to take one Prednisolone capsule each morning (AM) on the last 7 days of treatment.

Baseline Measures

	Placebo	FF/VI 100/25 µg PM	FF/VI 200/25 µg PM	Prednisolone 10 mg AM	Total
Number of Participants	58	56	56	15	185
Age, Continuous [units: Years] Mean (Standard Deviation)	36.1 (15.42)	34.4 (15.63)	34.0 (13.74)	37.5 (14.19)	35.1 (14.82)
Gender, Male/Female [units: Participants]					
Female	27	31	23	6	87
Male	31	25	33	9	98
Race/Ethnicity, Customized [units: Participants]					
African American/African Heritage	3	0	1	0	4
American Indian or Alaska Native	0	0	1	0	1
Asian - Japanese Heritage	0	0	1	0	1
White - White/Caucasian/European Heritage	55	56	53	15	179

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Ratio From Baseline of the Serum Cortisol Weighted Mean (0-24 Hours) on Day -1/1 (Baseline) and Day 42
Measure Description	Serum cortisol weighted mean was determined for each participant over the time period 0–12 hours on Day -1/1 (Baseline) and Day 42. Serum cortisol weighted mean was derived by dividing the area under the concentration-time curve (AUC; defined as thearea under the concentration-time curve from time zero up to 24 hours) by the sample collection time interval. The sample collection time interval is defined as the difference between the time of the last cortisol sample and the time of the first cortisol sample. Samples were collected at the following time points: 0 (first blood draw/pre-dose); 2, 4, 9, 12, 14, 16, 20, 22, and 24 hours (relative to the "0" time point). Because values are on a logged scale, the ratio of the endpoint to Baseline is presented, as it is a measure of the difference from Baseline.
Time Frame	Day -1/1 (Baseline) and Day 42
Safety Issue?	No

Analysis Population Description

Serum Cortisol (SC) Population: all participants in the Intent-to-Treat Population who did not have protocol deviations that were considered to affect the SC endpoint and whose serum samples were not considered to have confounding factors affecting results interpretation. Only those participant available at the specified time points were analzyed.

Reporting Groups

	Description
Placebo	Participants received placebo via a Dry Powder Inhaler (DPI) for 6 weeks, plus a placebo capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation from the DPI once daily at approximately the same time each evening for 6 weeks and to take one placebo capsule each morning on the last 7 days of treatment.
FF/VI 100/25 µg PM	Participants received Fluticasone Furoate/Vilanterol (FF/VI) 100/25 micrograms (µg) via a DPI for 6 weeks, plus a placebo capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation from the DPI once daily at approximately the same time each evening (PM) for 6 weeks and to take one placebo capsule each morning (AM) on the last 7 days of treatment.
FF/VI 200/25 µg PM	Participants received FF/VI 200/25 µg via a DPI for 6 weeks, plus a placebo capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation from the DPI once daily at approximately the same time each evening (PM) for 6 weeks and to take one placebo capsule each morning (AM) on the last 7 days of treatment.

	Description
Prednisolone 10 mg AM	Participants received placebo via a DPI for 6 weeks, plus a prednisolone 10 milligram (mg) capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation of placebo from the DPI once daily at approximately the same time each evening (PM) for 6 weeks and to take one Prednisolone capsule each morning (AM) on the last 7 days of treatment.

Measured Values

	Placebo	FF/VI 100/25 µg PM	FF/VI 200/25 µg PM	Prednisolone 10 mg AM
Number of Participants Analyzed	52	50	53	13
Ratio From Baseline of the Serum Cortisol Weighted Mean (0-24 Hours) on Day -1/1 (Baseline) and Day 42 [units: ratio from Baseline] Geometric Mean (Geometric Coefficient of Variation)	0.99 (29.6%)	0.99 (40.0%)	0.96 (27.2%)	0.32 (72.9%)

Statistical Analysis 1 for Ratio From Baseline of the Serum Cortisol Weighted Mean (0-24 Hours) on Day -1/1 (Baseline) and Day 42

Statistical Analysis Overview	Comparison Groups	Placebo, FF/VI 100/25 µg PM
	Comments	[Not specified.]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified.]

Method of Estimation	Estimation Parameter	Other [Ratio of least square gometric mean]
	Estimated Value	0.99
	Confidence Interval	(2-Sided) 95% 0.87 to 1.12
	Estimation Comments	Analysis was performed using Analysis of Covariance (ANCOVA) with covariates of region, sex, age, treatment, and the log of the Baseline values.

Statistical Analysis 2 for Ratio From Baseline of the Serum Cortisol Weighted Mean (0-24 Hours) on Day -1/1 (Baseline) and Day 42

Statistical Analysis Overview	Comparison Groups	Placebo, FF/VI 200/25 µg PM
	Comments	[Not specified.]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified.]
Method of Estimation	Estimation Parameter	Other [Ratio of least square gometric mean]
	Estimated Value	0.97
	Confidence Interval	(2-Sided) 95% 0.86 to 1.10
	Estimation Comments	Analysis was performed using ANCOVA with covariates of region, sex, age, treatment, and the log of the Baseline values.

Statistical Analysis 3 for Ratio From Baseline of the Serum Cortisol Weighted Mean (0-24 Hours) on Day -1/1 (Baseline) and Day 42

Statistical Analysis Overview	Comparison Groups	Placebo, Prednisolone 10 mg AM
	Comments	[Not specified.]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified.]
Method of Estimation	Estimation Parameter	Other [Ratio of least square gometric mean]
	Estimated Value	0.34
	Confidence Interval	(2-Sided) 95% 0.28 to 0.41
	Estimation Comments	Analysis performed using ANCOVA with covariates of region, sex, age, treatment, and the log of the Baseline values.

2. Secondary Outcome Measure:

Measure Title	Ratio From Baseline of the Serum Cortisol Area Under the Concentration-time Curve (AUC) (0-24 Hour) on Day -1/1 (Baseline) and Day 42
Measure Description	Area under the plasma drug concentration-time (AUC[0-24 hour]) curve from time zero (pre-dose) to the last time of quantifiable serum cortisol concentration at 24 hours post-dose on Day -1/1 (Baseline) and Day 42 was measured. AUC reflects the actual body exposure to drug over a specified period of time after administration of a dose. Samples were collected at the following times: 0 (immediately pre-dose inhaled study drug); post-dose at 5 minutes (min), 15 min, 30 min, and 1 hour (hr), 2 hr, 4 hr, 9 hr, 12 hr, 16 hr, 20 hr, and 24 hr. Because values are on a logged scale, the ratio of the endpoint to Baseline is presented, as it is a measure of the difference from Baseline.
Time Frame	Day -1/1 (Baseline) and Day 42
Safety Issue?	No

Analysis Population Description

SC Population. Only those participants available at the specified time points were analyzed.

Reporting Groups

	Description
Placebo	Participants received placebo via a Dry Powder Inhaler (DPI) for 6 weeks, plus a placebo capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation from the DPI once daily at approximately the same time each evening for 6 weeks and to take one placebo capsule each morning on the last 7 days of treatment.
FF/VI 100/25 µg PM	Participants received Fluticasone Furoate/Vilanterol (FF/VI) 100/25 micrograms (µg) via a DPI for 6 weeks, plus a placebo capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation from the DPI once daily at approximately the same time each evening (PM) for 6 weeks and to take one placebo capsule each morning (AM) on the last 7 days of treatment.
FF/VI 200/25 µg PM	Participants received FF/VI 200/25 µg via a DPI for 6 weeks, plus a placebo capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation from the DPI once daily at approximately the same time each evening (PM) for 6 weeks and to take one placebo capsule each morning (AM) on the last 7 days of treatment.

	Description
Prednisolone 10 mg AM	Participants received placebo via a DPI for 6 weeks, plus a prednisolone 10 milligram (mg) capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation of placebo from the DPI once daily at approximately the same time each evening (PM) for 6 weeks and to take one Prednisolone capsule each morning (AM) on the last 7 days of treatment.

Measured Values

	Placebo	FF/VI 100/25 µg PM	FF/VI 200/25 µg PM	Prednisolone 10 mg AM
Number of Participants Analyzed	52	50	53	13
Ratio From Baseline of the Serum Cortisol Area Under the Concentration-time Curve (AUC) (0-24 Hour) on Day -1/1 (Baseline) and Day 42 [units: ratio from Baseline] Geometric Mean (Geometric Coefficient of Variation)	0.99 (29.6%)	0.99 (40.1%)	0.97 (27.2%)	0.32 (71.9%)

3. Secondary Outcome Measure:

Measure Title	Ratio From Baseline of Serum Cortisol Trough (0-24 Hours) at Day -1/1 (Baseline) and Day 42
Measure Description	Serum cortisol trough is defined as the minimum value of serum cortisol measured over the 24-hour period. Samples were collected at the following times: 0 (immediately pre-dose inhaled study drug); post-dose at 5 minutes (min), 15 min, 30 min, and 1 hour (hr), 2 hr, 4 hr, 9 hr, 12 hr, 16 hr, 20 hr, and 24 hr. Because values are on a logged scale, the ratio of the endpoint to Baseline is presented, as it is a measure of the difference from Baseline.
Time Frame	Day -1/1 (Baseline) and Day 42
Safety Issue?	No

Analysis Population Description

SC Population. Only those participants available at the specified time points were analyzed.

Reporting Groups

	Description
Placebo	Participants received placebo via a Dry Powder Inhaler (DPI) for 6 weeks, plus a placebo capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation from the DPI once daily at approximately the same time each evening for 6 weeks and to take one placebo capsule each morning on the last 7 days of treatment.
FF/VI 100/25 µg PM	Participants received Fluticasone Furoate/Vilanterol (FF/VI) 100/25 micrograms (µg) via a DPI for 6 weeks, plus a placebo capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation from the DPI once daily at approximately the same time each evening (PM) for 6 weeks and to take one placebo capsule each morning (AM) on the last 7 days of treatment.
FF/VI 200/25 µg PM	Participants received FF/VI 200/25 µg via a DPI for 6 weeks, plus a placebo capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation from the DPI once daily at approximately the same time each evening (PM) for 6 weeks and to take one placebo capsule each morning (AM) on the last 7 days of treatment.
Prednisolone 10 mg AM	Participants received placebo via a DPI for 6 weeks, plus a prednisolone 10 milligram (mg) capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation of placebo from the DPI once daily at approximately the same time each evening (PM) for 6 weeks and to take one Prednisolone capsule each morning (AM) on the last 7 days of treatment.

Measured Values

	Placebo	FF/VI 100/25 µg PM	FF/VI 200/25 µg PM	Prednisolone 10 mg AM
Number of Participants Analyzed	52	51	53	13
Ratio From Baseline of Serum Cortisol Trough (0-24 Hours) at Day -1/1 (Baseline) and Day 42 [units: ratio from Baseline] Geometric Mean (Geometric Coefficient of Variation)	1.04 (88.2%)	0.84 (88.7%)	0.73 (80.7%)	0.28 (82.3%)

4. Secondary Outcome Measure:

Measure Title	Ratio From Baseline of 0-24 Hour Urinary Free Cortisol Excretion on Day -1/1 (Baseline) and Day 42

Measure Description	A 24-hour urine sample was collected for the measurement of 24-hour urinary cortisol excretion at Day -1/1 (Baseline) and Day 42. Only those participants available at the specified time points were analyzed. Because values are on a logged scale, the ratio of the endpoint to Baseline is presented, as it is a measure of the difference from Baseline.
Time Frame	Day -1/1 (Baseline) and Day 42
Safety Issue?	No

Analysis Population Description

Urine Cortisol (UC) Population: all participants in the ITT Population who did not have protocol deviations that were considered to affect the urine cortisol endpoint and whose urine samples were not considered to have confounding factors that would affect the interpretation of the results.

Reporting Groups

	Description
Placebo	Participants received placebo via a Dry Powder Inhaler (DPI) for 6 weeks, plus a placebo capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation from the DPI once daily at approximately the same time each evening for 6 weeks and to take one placebo capsule each morning on the last 7 days of treatment.
FF/VI 100/25 µg PM	Participants received Fluticasone Furoate/Vilanterol (FF/VI) 100/25 micrograms (µg) via a DPI for 6 weeks, plus a placebo capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation from the DPI once daily at approximately the same time each evening (PM) for 6 weeks and to take one placebo capsule each morning (AM) on the last 7 days of treatment.
FF/VI 200/25 µg PM	Participants received FF/VI 200/25 µg via a DPI for 6 weeks, plus a placebo capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation from the DPI once daily at approximately the same time each evening (PM) for 6 weeks and to take one placebo capsule each morning (AM) on the last 7 days of treatment.
Prednisolone 10 mg AM	Participants received placebo via a DPI for 6 weeks, plus a prednisolone 10 milligram (mg) capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation of placebo from the DPI once daily at approximately the same time each evening (PM) for 6 weeks and to take one Prednisolone capsule each morning (AM) on the last 7 days of treatment.

Measured Values

	Placebo	FF/VI 100/25 µg PM	FF/VI 200/25 µg PM	Prednisolone 10 mg AM
Number of Participants Analyzed	49	47	53	12
Ratio From Baseline of 0-24 Hour Urinary Free Cortisol Excretion on Day -1/1 (Baseline) and Day 42 [units: ratio from Baseline] Geometric Mean (Geometric Coefficient of Variation)	0.87 (77.923%)	1.03 (110.952%)	0.92 (96.312%)	0.40 (204.433%)

5. Secondary Outcome Measure:

Measure Title	Plasma FF and VI Pharmacokinetic (PK) Concentration
Measure Description	Plasma FF and VI Pharmacokinetic (PK) Concentration were estimates at the following time points:0 (immediately pre-dose inhaled study drug), and post-dose at 5 min, 15 min, 30 min, and 1 hr, 2 hr, 4 hr, 9 hr, 12 hr, 16 hr, 20 hr, 24 hr on Day 42. Only those participants available at the specified time points were analyzed (represented by n=X, X, X, X in the category titles). Different participants may have been analyzed at different time points, so the overall number of participants analyzed reflects everyone in the Pharmacokinetic Population.
Time Frame	Day 42
Safety Issue?	No

Analysis Population Description

Pharmacokinetic (PK) Population: all participants in the ITT Population for whom a pharmacokinetic sample was obtained and analyzed.

Reporting Groups

	Description
Placebo	Participants received placebo via a Dry Powder Inhaler (DPI) for 6 weeks, plus a placebo capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation from the DPI once daily at approximately the same time each evening for 6 weeks and to take one placebo capsule each morning on the last 7 days of treatment.

	Description
FF/VI 100/25 µg PM	Participants received Fluticasone Furoate/Vilanterol (FF/VI) 100/25 micrograms (µg) via a DPI for 6 weeks, plus a placebo capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation from the DPI once daily at approximately the same time each evening (PM) for 6 weeks and to take one placebo capsule each morning (AM) on the last 7 days of treatment.
FF/VI 200/25 µg PM	Participants received FF/VI 200/25 µg via a DPI for 6 weeks, plus a placebo capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation from the DPI once daily at approximately the same time each evening (PM) for 6 weeks and to take one placebo capsule each morning (AM) on the last 7 days of treatment.
Prednisolone 10 mg AM	Participants received placebo via a DPI for 6 weeks, plus a prednisolone 10 milligram (mg) capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation of placebo from the DPI once daily at approximately the same time each evening (PM) for 6 weeks and to take one Prednisolone capsule each morning (AM) on the last 7 days of treatment.

Measured Values

	Placebo	FF/VI 100/25 µg PM	FF/VI 200/25 µg PM	Prednisolone 10 mg AM
Number of Participants Analyzed	0	54	56	0
Plasma FF and VI Pharmacokinetic (PK) Concentration [units: picograms per milliliter (pg/mL)] Mean (Standard Deviation)				
FF, 0 hour, n=53, 54		3.57 (NA) [1]	10.02 (NA) [1]	
FF, 5 minutes post-dose, n=51, 54		16.65 (10.191)	25.55 (14.438)	
FF, 15 minutes post-dose, n=50, 54		16.35 (10.198)	28.84 (14.441)	
FF, 30 minutes post-dose, n=52, 52		17.12 (10.583)	30.68 (15.461)	
FF, 1 hour post-dose, n=54, 54		16.91 (9.637)	30.07 (15.540)	
FF, 2 hours post-dose, n=51, 53		15.00 (9.272)	30.20 (18.292)	
FF, 4 hours post-dose, n=54, 53		9.78 (NA) [1]	21.79 (11.597)	

	Placebo	FF/VI 100/25 µg PM	FF/VI 200/25 µg PM	Prednisolone 10 mg AM
FF, 9 hours post-dose, n=48, 52		6.20 (NA) [1]	15.99 (11.667)	
FF, 12 hours post-dose, n=51, 55		4.62 (NA) [1]	13.37 (9.670)	
FF, 16 hours post-dose, n=49, 52		2.55 (NA) [1]	11.73 (NA) [1]	
FF, 20 hours post-dose, n=51, 51		1.74 (NA) [1]	9.28 (NA) [1]	
FF, 24 hours post-dose, n=48, 53		1.55 (NA) [1]	7.58 (NA) [1]	
VI, 0 hours, n=52, 54		2.57 (NA) [1]	7.95 (NA) [1]	
VI, 5 minutes post-dose, n=50, 54		85.22 (70.582)	90.54 (88.794)	
VI, 15 minutes post-dose, n=48, 55		62.94 (52.020)	72.53 (55.271)	
VI, 30 minutes post-dose, n=51, 55		33.38 (33.932)	36.88 (33.157)	
VI, 1 hour post-dose, n=52, 53		14.63 (NA) [1]	20.07 (NA) [1]	
VI, 2 hours post-dose, n=52, 55		7.09 (NA) [1]	6.06 (NA) [1]	
VI, 4 hours post-dose, n=52, 54		0.00 (NA) [1]	0.45 (NA) [1]	
VI, 9 hours post-dose, n=52, 55		0.00 (NA) [1]	0.47 (NA) [1]	
VI, 12 hours post-dose, n=52, 55		0.00 (NA) [1]	1.21 (NA) [1]	
VI, 16 hours post-dose, n=51, 52		0.00 (NA) [1]	4.76 (NA) [1]	
VI, 20 hours post-dose, n=50, 54		0.00 (NA) [1]	0.00 (NA) [1]	
VI, 24 hours post-dose, n=52, 55		1.19 (NA) [1]	0.00 (NA) [1]	

[1] Values below 10 pg/mL are below the limit of quantification and are imputed. Standard deviation is not displayed if >30% of values are imputed.

6. Secondary Outcome Measure:

Measure Title	AUC(0-t) and AUC(0-24) for FF on Day 42

Measure Description	Area under the plasma drug concentration-time (AUC[0-t]) curve from time zero (pre-dose) to the last time of quantifiable FF concentration and AUC(0-24) is the concentration time curve from zero (pre-dose) to 24 hours of quantifiable FF concentration on Day 42 was measured. AUC reflects the actual body exposure to drug over a specified period of time after administration of a dose. Samples were collected at the following times: 0 (immediately pre-dose inhaled study drug); post-dose at 5 minutes (min), 15 min, 30 min, and 1 hour (hr), 2 hr, 4 hr, 9 hr, 12 hr, 16 hr, 20 hr, and 24 hr post-dose on Day 42.
Time Frame	Day 42
Safety Issue?	No

Analysis Population Description

PK Population. Only those participants available at the specified time points were analyzed (represented by n=X, X, X, X in the category titles). Different participants may have been analyzed for different parameters, so the overall number of participants analyzed reflects everyone in the PK Population.

Reporting Groups

	Description
Placebo	Participants received placebo via a Dry Powder Inhaler (DPI) for 6 weeks, plus a placebo capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation from the DPI once daily at approximately the same time each evening for 6 weeks and to take one placebo capsule each morning on the last 7 days of treatment.
FF/VI 100/25 µg PM	Participants received Fluticasone Furoate/Vilanterol (FF/VI) 100/25 micrograms (µg) via a DPI for 6 weeks, plus a placebo capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation from the DPI once daily at approximately the same time each evening (PM) for 6 weeks and to take one placebo capsule each morning (AM) on the last 7 days of treatment.
FF/VI 200/25 µg PM	Participants received FF/VI 200/25 µg via a DPI for 6 weeks, plus a placebo capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation from the DPI once daily at approximately the same time each evening (PM) for 6 weeks and to take one placebo capsule each morning (AM) on the last 7 days of treatment.
Prednisolone 10 mg AM	Participants received placebo via a DPI for 6 weeks, plus a prednisolone 10 milligram (mg) capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation of placebo from the DPI once daily at approximately the same time each evening (PM) for 6 weeks and to take one Prednisolone capsule each morning (AM) on the last 7 days of treatment.

Measured Values

	Placebo	FF/VI 100/25 µg PM	FF/VI 200/25 µg PM	Prednisolone 10 mg AM
Number of Participants Analyzed	0	54	56	0
AUC(0-t) and AUC(0-24) for FF on Day 42 [units: picograms*hour per milliliter (pg*hr/mL)] Geometric Mean (95% Confidence Interval)				
AUC(0-t), n=54, 55		58.842 (37.706 to 91.825)	221.694 (152.697 to 321.868)	
AUC(0-24), n=49, 53		NA (NA to NA) [1]	324.015 (267.233 to 392.862)	

[1] Data are not available because >=50% of values were non-calculable due to non-quantifiable concentrations (below the level of detection).

7. Secondary Outcome Measure:

Measure Title	Cmax for FF on Day 42
Measure Description	Cmax is defined as the maximum observed concentration on Day 42. Samples were collected at the following times: 0 (immediately pre-dose inhaled study drug); post-dose at 5 minutes (min), 15 min, 30 min, and 1 hour (hr), 2 hr, 4 hr, 9 hr, 12 hr, 16 hr, 20 hr, and 24 hr post-dose on Day 42.
Time Frame	Day 42
Safety Issue?	No

Analysis Population Description

PK Population. Only those participants available at the specified time points were analyzed.

Reporting Groups

	Description
Placebo	Participants received placebo via a Dry Powder Inhaler (DPI) for 6 weeks, plus a placebo capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation from the DPI once daily at approximately the same time each evening for 6 weeks and to take one placebo capsule each morning on the last 7 days of treatment.
FF/VI 100/25 µg PM	Participants received Fluticasone Furoate/Vilanterol (FF/VI) 100/25 micrograms (µg) via a DPI for 6 weeks, plus a placebo capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation from the DPI once daily at approximately the same time each evening (PM) for 6 weeks and to take one placebo capsule each morning (AM) on the last 7 days of treatment.
FF/VI 200/25 µg PM	Participants received FF/VI 200/25 µg via a DPI for 6 weeks, plus a placebo capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation from the DPI once daily at approximately the same time each evening (PM) for 6 weeks and to take one placebo capsule each morning (AM) on the last 7 days of treatment.
Prednisolone 10 mg AM	Participants received placebo via a DPI for 6 weeks, plus a prednisolone 10 milligram (mg) capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation of placebo from the DPI once daily at approximately the same time each evening (PM) for 6 weeks and to take one Prednisolone capsule each morning (AM) on the last 7 days of treatment.

Measured Values

	Placebo	FF/VI 100/25 µg PM	FF/VI 200/25 µg PM	Prednisolone 10 mg AM
Number of Participants Analyzed	0	54	55	0
Cmax for FF on Day 42 [units: picograms per milliliter (pg/mL)] Geometric Mean (95% Confidence Interval)		19.388 (16.796 to 22.379)	33.017 (28.586 to 38.135)	

8. Secondary Outcome Measure:

Measure Title	Tmax and Tlast of FF at Day 42

Measure Description	tmax is defined as the time to reach the observed maximum concentration, and tlast is defined as the time of the last observed quantifiable concentration on Day 42. Samples were collected at the following times: 0 (immediately pre-dose inhaled study drug); post-dose at 5 minutes (min), 15 min, 30 min, and 1hour (hr), 2 hr, 4 hr, 9 hr, 12 hr, 16 hr, 20 hr, and 24 hr post-dose on Day 42.
Time Frame	Day 42
Safety Issue?	No

Analysis Population Description

PK Population. Only those participants available at the specified time points were analyzed.

Reporting Groups

	Description
Placebo	Participants received placebo via a Dry Powder Inhaler (DPI) for 6 weeks, plus a placebo capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation from the DPI once daily at approximately the same time each evening for 6 weeks and to take one placebo capsule each morning on the last 7 days of treatment.
FF/VI 100/25 µg PM	Participants received Fluticasone Furoate/Vilanterol (FF/VI) 100/25 micrograms (µg) via a DPI for 6 weeks, plus a placebo capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation from the DPI once daily at approximately the same time each evening (PM) for 6 weeks and to take one placebo capsule each morning (AM) on the last 7 days of treatment.
FF/VI 200/25 µg PM	Participants received FF/VI 200/25 µg via a DPI for 6 weeks, plus a placebo capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation from the DPI once daily at approximately the same time each evening (PM) for 6 weeks and to take one placebo capsule each morning (AM) on the last 7 days of treatment.
Prednisolone 10 mg AM	Participants received placebo via a DPI for 6 weeks, plus a prednisolone 10 milligram (mg) capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation of placebo from the DPI once daily at approximately the same time each evening (PM) for 6 weeks and to take one Prednisolone capsule each morning (AM) on the last 7 days of treatment.

Measured Values

	Placebo	FF/VI 100/25 µg PM	FF/VI 200/25 µg PM	Prednisolone 10 mg AM
Number of Participants Analyzed	0	54	55	0
Tmax and Tlast of FF at Day 42 [units: hours] Median (Full Range)				
tmax		0.500 (0.03 to 8.97)	0.500 (0.07 to 4.00)	
tlast		9.000 (0.98 to 24.00)	20.042 (0.95 to 24.08)	

9. Secondary Outcome Measure:

Measure Title	AUC(0-t) for VI on Day 42
Measure Description	Area under the concentration-time (AUC[0-t]) curve from time zero (pre-dose) to the last time of quantifiable VI concentration on Day 42 was measured. Samples were collected at the following times: 0 (immediately pre-dose inhaled study drug); post-dose at 5 minutes (min), 15 min, 30 min, and 1 hour (hr), 2 hr, 4 hr, 9 hr, 12 hr, 16 hr, 20 hr, and 24 hr post-dose on Day 42.
Time Frame	Day 42
Safety Issue?	No

Analysis Population Description

PK Population. Only those participants available at the specified time points were analyzed.

Reporting Groups

	Description
Placebo	Participants received placebo via a Dry Powder Inhaler (DPI) for 6 weeks, plus a placebo capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation from the DPI once daily at approximately the same time each evening for 6 weeks and to take one placebo capsule each morning on the last 7 days of treatment.

	Description
FF/VI 100/25 µg PM	Participants received Fluticasone Furoate/Vilanterol (FF/VI) 100/25 micrograms (µg) via a DPI for 6 weeks, plus a placebo capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation from the DPI once daily at approximately the same time each evening (PM) for 6 weeks and to take one placebo capsule each morning (AM) on the last 7 days of treatment.
FF/VI 200/25 µg PM	Participants received FF/VI 200/25 µg via a DPI for 6 weeks, plus a placebo capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation from the DPI once daily at approximately the same time each evening (PM) for 6 weeks and to take one placebo capsule each morning (AM) on the last 7 days of treatment.
Prednisolone 10 mg AM	Participants received placebo via a DPI for 6 weeks, plus a prednisolone 10 milligram (mg) capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation of placebo from the DPI once daily at approximately the same time each evening (PM) for 6 weeks and to take one Prednisolone capsule each morning (AM) on the last 7 days of treatment.

Measured Values

	Placebo	FF/VI 100/25 µg PM	FF/VI 200/25 µg PM	Prednisolone 10 mg AM
Number of Participants Analyzed	0	52	55	0
AUC(0-t) for VI on Day 42 [units: picograms*hour per milliliter (pg*hr/mL)] Mean (Standard Deviation)		41.177 (53.9720)	66.937 (142.3461)	

10. Secondary Outcome Measure:

Measure Title	Cmax for VI on Day 42
Measure Description	Cmax is defined as the maximum observed concentration on Day 42. Samples were collected at the following times: 0 (immediately pre-dose inhaled study drug); post-dose at 5 minutes (min), 15 min, 30 min, and 1 hour (hr), 2 hr, 4 hr, 9 hr, 12 hr, 16 hr, 20 hr, and 24 hr post-dose on Day 42.
Time Frame	Day 42

Safety Issue?	No

Analysis Population Description

PK Population. Only those participants available at the specified time points were analyzed.

Reporting Groups

	Description
Placebo	Participants received placebo via a Dry Powder Inhaler (DPI) for 6 weeks, plus a placebo capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation from the DPI once daily at approximately the same time each evening for 6 weeks and to take one placebo capsule each morning on the last 7 days of treatment.
FF/VI 100/25 µg PM	Participants received Fluticasone Furoate/Vilanterol (FF/VI) 100/25 micrograms (µg) via a DPI for 6 weeks, plus a placebo capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation from the DPI once daily at approximately the same time each evening (PM) for 6 weeks and to take one placebo capsule each morning (AM) on the last 7 days of treatment.
FF/VI 200/25 µg PM	Participants received FF/VI 200/25 µg via a DPI for 6 weeks, plus a placebo capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation from the DPI once daily at approximately the same time each evening (PM) for 6 weeks and to take one placebo capsule each morning (AM) on the last 7 days of treatment.
Prednisolone 10 mg AM	Participants received placebo via a DPI for 6 weeks, plus a prednisolone 10 milligram (mg) capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation of placebo from the DPI once daily at approximately the same time each evening (PM) for 6 weeks and to take one Prednisolone capsule each morning (AM) on the last 7 days of treatment.

Measured Values

	Placebo	FF/VI 100/25 µg PM	FF/VI 200/25 µg PM	Prednisolone 10 mg AM
Number of Participants Analyzed	0	52	55	0
Cmax for VI on Day 42 [units: picograms per milliliter (pg/mL)] Mean (Standard Deviation)		101.227 (73.8233)	118.531 (86.8659)	

11. Secondary Outcome Measure:

Measure Title	Tmax and Tlast of VI at Day 42
Measure Description	tmax is defined as the time to reach the observed maximum concentration, and tlast is defined as the time of the last observed quantifiable VI concentration on Day 42. Samples were collected at the following times: 0 (immediately pre-dose inhaled study drug); post-dose at 5 minutes (min), 15 min, 30 min, and 1hour (hr), 2 hr, 4 hr, 9 hr, 12 hr, 16 hr, 20 hr, and 24 hr post-dose on Day 42.
Time Frame	Day 42
Safety Issue?	No

Analysis Population Description

PK Population. Only those participants available at the specified time points were analyzed.

Reporting Groups

	Description
Placebo	Participants received placebo via a Dry Powder Inhaler (DPI) for 6 weeks, plus a placebo capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation from the DPI once daily at approximately the same time each evening for 6 weeks and to take one placebo capsule each morning on the last 7 days of treatment.
FF/VI 100/25 µg PM	Participants received Fluticasone Furoate/Vilanterol (FF/VI) 100/25 micrograms (µg) via a DPI for 6 weeks, plus a placebo capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation from the DPI once daily at approximately the same time each evening (PM) for 6 weeks and to take one placebo capsule each morning (AM) on the last 7 days of treatment.
FF/VI 200/25 µg PM	Participants received FF/VI 200/25 µg via a DPI for 6 weeks, plus a placebo capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation from the DPI once daily at approximately the same time each evening (PM) for 6 weeks and to take one placebo capsule each morning (AM) on the last 7 days of treatment.

	Description
Prednisolone 10 mg AM	Participants received placebo via a DPI for 6 weeks, plus a prednisolone 10 milligram (mg) capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation of placebo from the DPI once daily at approximately the same time each evening (PM) for 6 weeks and to take one Prednisolone capsule each morning (AM) on the last 7 days of treatment.

Measured Values

	Placebo	FF/VI 100/25 µg PM	FF/VI 200/25 µg PM	Prednisolone 10 mg AM
Number of Participants Analyzed	0	52	55	0
Tmax and Tlast of VI at Day 42 [units: hours] Median (Full Range)				
tmax		0.083 (0.00 to 2.00)	0.083 (0.00 to 16.00)	
tlast		0.500 (0.03 to 2.00)	0.950 (0.08 to 16.00)	

12. Secondary Outcome Measure:

Measure Title	Number of Participants With Any Adverse Event (AE) or Any Serious Adverse Event (SAE) During the Treatment Period
Measure Description	An AE is defined as any untoward medical occurrence in a participant or clinical investigation participant, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. A serious adverse event (SAE) is defined as any untoward medical occurrence that, at any dose, results in death, is life threatening, requires hospitalization or prolongation of existing hospitalization, results in disability/incapacity, or is a congenital anomaly/birth defect. Medical or scientific judgment should be exercised in deciding whether reporting is appropriate in other situations. Refer to the General Adverse AE/SAE module for a complete list of AEs and SAEs.
Time Frame	From the start of study medication until Day 42 (Visit 5)/Early Withdrawal
Safety Issue?	No

Analysis Population Description

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

Reporting Groups

	Description
Placebo	Participants received placebo via a Dry Powder Inhaler (DPI) for 6 weeks, plus a placebo capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation from the DPI once daily at approximately the same time each evening for 6 weeks and to take one placebo capsule each morning on the last 7 days of treatment.
FF/VI 100/25 µg PM	Participants received Fluticasone Furoate/Vilanterol (FF/VI) 100/25 micrograms (µg) via a DPI for 6 weeks, plus a placebo capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation from the DPI once daily at approximately the same time each evening (PM) for 6 weeks and to take one placebo capsule each morning (AM) on the last 7 days of treatment.
FF/VI 200/25 µg PM	Participants received FF/VI 200/25 µg via a DPI for 6 weeks, plus a placebo capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation from the DPI once daily at approximately the same time each evening (PM) for 6 weeks and to take one placebo capsule each morning (AM) on the last 7 days of treatment.
Prednisolone 10 mg AM	Participants received placebo via a DPI for 6 weeks, plus a prednisolone 10 milligram (mg) capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation of placebo from the DPI once daily at approximately the same time each evening (PM) for 6 weeks and to take one Prednisolone capsule each morning (AM) on the last 7 days of treatment.

Measured Values

	Placebo	FF/VI 100/25 µg PM	FF/VI 200/25 µg PM	Prednisolone 10 mg AM
Number of Participants Analyzed	58	56	56	15
Number of Participants With Any Adverse Event (AE) or Any Serious Adverse Event (SAE) During the Treatment Period [units: Participants]				
Any AE	16	23	21	5
Any SAE	0	0	0	0

13. Secondary Outcome Measure:

Measure Title	Change From Baseline in Basophil, Eosinophil, Lymphocyte, Monocyte, and Segmented Neutrophil Values at Day 42/Early Withdrawal (EW)
Measure Description	Blood samples were collected for the measurement of basophils, eosinophils, lymphocytes, monocytes, and segmented neutrophils at Baseline and Day 42/EW. For all laboratory assessments, Baseline is the most recent recorded value at Screening or prior to Day -1/1. Change from Baseline was calculated as the Day 42/EW value minus the Baseline value.
Time Frame	Baseline and Day 42/Early Withdrawal (EW)
Safety Issue?	No

Analysis Population Description

ITT Population. Only those participants available at the specified time points were analyzed (represented by n=X, X, X, X in the category titles). Different participants may have been analyzed for different parameters, so the overall number of participants analyzed reflects everyone in the ITT Population.

Reporting Groups

	Description
Placebo	Participants received placebo via a Dry Powder Inhaler (DPI) for 6 weeks, plus a placebo capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation from the DPI once daily at approximately the same time each evening for 6 weeks and to take one placebo capsule each morning on the last 7 days of treatment.
FF/VI 100/25 µg PM	Participants received Fluticasone Furoate/Vilanterol (FF/VI) 100/25 micrograms (µg) via a DPI for 6 weeks, plus a placebo capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation from the DPI once daily at approximately the same time each evening (PM) for 6 weeks and to take one placebo capsule each morning (AM) on the last 7 days of treatment.
FF/VI 200/25 µg PM	Participants received FF/VI 200/25 µg via a DPI for 6 weeks, plus a placebo capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation from the DPI once daily at approximately the same time each evening (PM) for 6 weeks and to take one placebo capsule each morning (AM) on the last 7 days of treatment.

	Description
Prednisolone 10 mg AM	Participants received placebo via a DPI for 6 weeks, plus a prednisolone 10 milligram (mg) capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation of placebo from the DPI once daily at approximately the same time each evening (PM) for 6 weeks and to take one Prednisolone capsule each morning (AM) on the last 7 days of treatment.

Measured Values

	Placebo	FF/VI 100/25 µg PM	FF/VI 200/25 µg PM	Prednisolone 10 mg AM
Number of Participants Analyzed	58	56	56	15
Change From Baseline in Basophil, Eosinophil, Lymphocyte, Monocyte, and Segmented Neutrophil Values at Day 42/Early Withdrawal (EW) [units: Percentage] Mean (Standard Deviation)				
Basophils, Day 42, n=50, 47, 53, 11	0.05 (0.354)	0.04 (0.356)	-0.05 (0.350)	-0.08 (0.223)
Basophils, EW, n=2, 2, 0, 0	-0.10 (0.141)	0.10 (0.141)	NA (NA) [1]	NA (NA) [1]
Eosinophils, Day 42, n=50, 47, 53, 11	0.57 (2.837)	0.27 (2.073)	-0.99 (2.664)	-1.11 (1.488)
Eosinophils, EW, n=2, 2, 0, 0	0.50 (0.849)	-0.55 (2.051)	NA (NA) [1]	NA (NA) [1]
Lymphocytes, Day 42, n=50, 47, 53, 11	1.09 (6.836)	1.54 (8.853)	-1.32 (7.844)	-2.48 (14.319)
Lymphocytes, EW, n=2, 2, 0, 0	2.90 (10.607)	2.00 (2.263)	NA (NA) [1]	NA (NA) [1]
Monocytes, Day 42, n=50, 47, 53, 11	-0.51 (2.074)	-0.03 (3.333)	0.07 (2.581)	-0.70 (1.977)
Monocytes, EW, n=2, 2, 0, 0	-1.00 (0.424)	-0.70 (3.111)	NA (NA) [1]	NA (NA) [1]
Segmented Neutrophils, Day 42, n=50, 47, 53, 11	-1.16 (8.291)	-1.85 (10.279)	2.30 (9.583)	4.37 (15.667)
Segmented Neutrophils, EW, n=2, 2, 0, 0	-2.30 (11.738)	-0.85 (3.465)	NA (NA) [1]	NA (NA) [1]

[1] Data are not available (missing) for some participants who withdrew from the study early.

14. Secondary Outcome Measure:

Measure Title	Change From Baseline in Eosinophil, Total Neutrophil, Platelet, and White Blood Cell (WBC) Count Values at Day 42/EW
Measure Description	Blood samples were collected for the measurement of eosinophils, total neutrophils, platelets, and WBC count at Baseline and Day 42/EW. For all laboratory assessments, Baseline is the most recent recorded value at Screening or prior to Day -1/1. Change from Baseline was calculated as the Day 42/EW value minus the Baseline value.
Time Frame	Baseline and Day 42/EW
Safety Issue?	No

Analysis Population Description

ITT Population. Only those participants available at the specified time points were analyzed (represented by n=X, X, X, X in the category titles). Different participants may have been analyzed for different parameters, so the overall number of participants analyzed reflects everyone in the ITT Population.

Reporting Groups

	Description
Placebo	Participants received placebo via a Dry Powder Inhaler (DPI) for 6 weeks, plus a placebo capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation from the DPI once daily at approximately the same time each evening for 6 weeks and to take one placebo capsule each morning on the last 7 days of treatment.
FF/VI 100/25 µg PM	Participants received Fluticasone Furoate/Vilanterol (FF/VI) 100/25 micrograms (µg) via a DPI for 6 weeks, plus a placebo capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation from the DPI once daily at approximately the same time each evening (PM) for 6 weeks and to take one placebo capsule each morning (AM) on the last 7 days of treatment.
FF/VI 200/25 µg PM	Participants received FF/VI 200/25 µg via a DPI for 6 weeks, plus a placebo capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation from the DPI once daily at approximately the same time each evening (PM) for 6 weeks and to take one placebo capsule each morning (AM) on the last 7 days of treatment.

	Description
Prednisolone 10 mg AM	Participants received placebo via a DPI for 6 weeks, plus a prednisolone 10 milligram (mg) capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation of placebo from the DPI once daily at approximately the same time each evening (PM) for 6 weeks and to take one Prednisolone capsule each morning (AM) on the last 7 days of treatment.

Measured Values

	Placebo	FF/VI 100/25 µg PM	FF/VI 200/25 µg PM	Prednisolone 10 mg AM
Number of Participants Analyzed	58	56	56	15
Change From Baseline in Eosinophil, Total Neutrophil, Platelet, and White Blood Cell (WBC) Count Values at Day 42/EW [units: 10^9 cells per liter (GI/L)] Mean (Standard Deviation)				
Eosinophils, Day 42, n=50, 47, 53, 11	0.066 (0.2282)	0.044 (0.1608)	-0.022 (0.1805)	-0.036 (0.0803)
Eosinophils, EW, n=2, 2, 0, 0	0.015 (0.0071)	-0.060 (0.1697)	NA (NA) [1]	NA (NA) [1]
Total Neutrophils, Day 42, n=50, 47, 53, 11	0.017 (1.3317)	0.289 (1.4873)	0.704 (1.2403)	1.435 (2.5515)
Total Neutrophils, EW, n=2, 2, 0, 0	-0.420 (1.7253)	-1.165 (0.9970)	NA (NA) [1]	NA (NA) [1]
Platelets, Day 42, n=50, 48, 51, 11	-11.1 (28.72)	-8.2 (31.33)	-3.9 (25.31)	16.1 (16.50)
Platelets, EW, n=1, 2, 0, 0	-2.0 (NA) [1]	-39.5 (28.99)	NA (NA) [1]	NA (NA) [1]
WBC Day 42, n=50, 47, 53, 11	0.22 (1.584)	0.71 (1.787)	0.96 (1.367)	1.69 (2.418)
WBC EW, n=2, 2	-0.25 (1.344)	-1.65 (0.778)	NA (NA) [1]	NA (NA) [1]

[1] Data are not available (missing) for some participants who withdrew from the study early.

15. Secondary Outcome Measure:

Measure Title	Change From Baseline in Hemoglobin Values at Day 42/EW

Measure Description	Blood samples were collected for the measurement of hemoglobin at Baseline and Day 42/EW. For all laboratory assessments, Baseline is the most recent recorded value at Screening or prior to Day -1/1. Change from Baseline was calculated as the Day 42/EW value minus the Baseline value.
Time Frame	Baseline and Day 42/EW
Safety Issue?	No

Analysis Population Description

ITT Population. Only those participants available at the specified time points were analyzed (represented by n=X, X, X, X in the category titles). Different participants may have been analyzed at different time points, so the overall number of participants analyzed reflects everyone in the ITT Population.

Reporting Groups

	Description
Placebo	Participants received placebo via a Dry Powder Inhaler (DPI) for 6 weeks, plus a placebo capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation from the DPI once daily at approximately the same time each evening for 6 weeks and to take one placebo capsule each morning on the last 7 days of treatment.
FF/VI 100/25 µg PM	Participants received Fluticasone Furoate/Vilanterol (FF/VI) 100/25 micrograms (µg) via a DPI for 6 weeks, plus a placebo capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation from the DPI once daily at approximately the same time each evening (PM) for 6 weeks and to take one placebo capsule each morning (AM) on the last 7 days of treatment.
FF/VI 200/25 µg PM	Participants received FF/VI 200/25 µg via a DPI for 6 weeks, plus a placebo capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation from the DPI once daily at approximately the same time each evening (PM) for 6 weeks and to take one placebo capsule each morning (AM) on the last 7 days of treatment.
Prednisolone 10 mg AM	Participants received placebo via a DPI for 6 weeks, plus a prednisolone 10 milligram (mg) capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation of placebo from the DPI once daily at approximately the same time each evening (PM) for 6 weeks and to take one Prednisolone capsule each morning (AM) on the last 7 days of treatment.

Measured Values

	Placebo	FF/VI 100/25 µg PM	FF/VI 200/25 µg PM	Prednisolone 10 mg AM
Number of Participants Analyzed	58	56	56	15
Change From Baseline in Hemoglobin Values at Day 42/EW [units: Grams per liter (g/L)] Mean (Standard Deviation)				
Day 42, n=50, 48, 53, 11	-5.8 (10.28)	-6.2 (6.23)	-5.7 (6.59)	-3.5 (9.27)
EW, n=2, 2, 0, 0	-10.5 (2.12)	-3.0 (8.49)	NA (NA) [1]	NA (NA) [1]

[1] Data are not available (missing) for some participants who withdrew from the study early.

16. Secondary Outcome Measure:

Measure Title	Change From Baseline in Hematocrit Values at Day 42/EW
Measure Description	Blood samples were collected for the measurement of hematocrit at Baseline and Day 42/EW. For all laboratory assessments, Baseline is the most recent recorded value at Screening or prior to Day -1/1. Change from Baseline was calculated as the Day 42/EW value minus the Baseline value.
Time Frame	Baseline and Day 42/EW
Safety Issue?	No

Analysis Population Description

ITT Population. Only those participants available at the specified time points were analyzed (represented by n=X, X, X, X in the category titles). Different participants may have been analyzed at different time points, so the overall number of participants analyzed reflects everyone in the ITT Population.

Reporting Groups

	Description
Placebo	Participants received placebo via a Dry Powder Inhaler (DPI) for 6 weeks, plus a placebo capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation from the DPI once daily at approximately the same time each evening for 6 weeks and to take one placebo capsule each morning on the last 7 days of treatment.

	Description
FF/VI 100/25 µg PM	Participants received Fluticasone Furoate/Vilanterol (FF/VI) 100/25 micrograms (µg) via a DPI for 6 weeks, plus a placebo capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation from the DPI once daily at approximately the same time each evening (PM) for 6 weeks and to take one placebo capsule each morning (AM) on the last 7 days of treatment.
FF/VI 200/25 µg PM	Participants received FF/VI 200/25 µg via a DPI for 6 weeks, plus a placebo capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation from the DPI once daily at approximately the same time each evening (PM) for 6 weeks and to take one placebo capsule each morning (AM) on the last 7 days of treatment.
Prednisolone 10 mg AM	Participants received placebo via a DPI for 6 weeks, plus a prednisolone 10 milligram (mg) capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation of placebo from the DPI once daily at approximately the same time each evening (PM) for 6 weeks and to take one Prednisolone capsule each morning (AM) on the last 7 days of treatment.

Measured Values

	Placebo	FF/VI 100/25 µg PM	FF/VI 200/25 µg PM	Prednisolone 10 mg AM
Number of Participants Analyzed	58	56	56	15
Change From Baseline in Hematocrit Values at Day 42/EW [units: Proportion of 1] Mean (Standard Deviation)				
Day 42, n=50, 48, 53, 11	-0.0123 (0.02957)	-0.0120 (0.02125)	-0.0114 (0.02151)	-0.0072 (0.02955)
EW, n=2, 2, 0, 0	-0.0175 (0.00071)	-0.0050 (0.02263)	NA (NA) [1]	NA (NA) [1]

[1] Data are not available (missing) for some participants who withdrew from the study early.

17. Secondary Outcome Measure:

Measure Title	Change From Baseline in Alanine Amino Transferase (ALT), Alkaline Phosphatase (ALP), Aspartate Amino Transferase (AST), Creatine Kinase (CK), and Gamma Glutamyl Transferase (GGT) Values at Day 42/EW
Measure Description	Blood samples were collected for the measurement of ALT, ALP, AST, CK, and GGT at Baseline and Day 42/EW. For all laboratory assessments, Baseline is the most recent recorded value at Screening or prior to Day -1/1. Change from Baseline was calculated as the Day 42/EW value minus the Baseline value.
Time Frame	Baseline and Day 42/EW
Safety Issue?	No

Analysis Population Description

ITT Population. Only those participants available at the specified time points were analyzed (represented by n=X, X, X, X in the category titles). Different participants may have been analyzed for different parameters, so the overall number of participants analyzed reflects everyone in the ITT Population.

Reporting Groups

	Description
Placebo	Participants received placebo via a Dry Powder Inhaler (DPI) for 6 weeks, plus a placebo capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation from the DPI once daily at approximately the same time each evening for 6 weeks and to take one placebo capsule each morning on the last 7 days of treatment.
FF/VI 100/25 µg PM	Participants received Fluticasone Furoate/Vilanterol (FF/VI) 100/25 micrograms (µg) via a DPI for 6 weeks, plus a placebo capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation from the DPI once daily at approximately the same time each evening (PM) for 6 weeks and to take one placebo capsule each morning (AM) on the last 7 days of treatment.
FF/VI 200/25 µg PM	Participants received FF/VI 200/25 µg via a DPI for 6 weeks, plus a placebo capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation from the DPI once daily at approximately the same time each evening (PM) for 6 weeks and to take one placebo capsule each morning (AM) on the last 7 days of treatment.
Prednisolone 10 mg AM	Participants received placebo via a DPI for 6 weeks, plus a prednisolone 10 milligram (mg) capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation of placebo from the DPI once daily at approximately the same time each evening (PM) for 6 weeks and to take one Prednisolone capsule each morning (AM) on the last 7 days of treatment.

Measured Values

	Placebo	FF/VI 100/25 µg PM	FF/VI 200/25 µg PM	Prednisolone 10 mg AM
Number of Participants Analyzed	58	56	56	15
Change From Baseline in Alanine Amino Transferase (ALT), Alkaline Phosphatase (ALP), Aspartate Amino Transferase (AST), Creatine Kinase (CK), and Gamma Glutamyl Transferase (GGT) Values at Day 42/EW [units: International units per liter (IU/L)] Mean (Standard Deviation)				
ALT, Day 42, n=55, 51, 55, 12	-1.3 (13.05)	-2.0 (8.49)	-2.2 (10.86)	0.8 (3.33)
ALT, EW, n=2, 2, 0, 0	-5.0 (8.49)	0.5 (2.12)	NA (NA) [1]	NA (NA) [1]
ALP, Day 42, n=55, 51, 55, 12	-6.8 (11.06)	-2.1 (13.96)	-2.6 (8.33)	-4.9 (9.86)
ALP, EW, n=2, 2, 0, 0	1.5 (9.19)	-1.0 (1.41)	NA (NA) [1]	NA (NA) [1]
AST, Day 42, n=54, 50, 51, 12	-0.1 (12.42)	-1.4 (6.82)	-0.6 (6.91)	-1.8 (5.67)
AST, EW, n=2, 2, 0, 0	0.5 (0.71)	0.0 (1.41)	NA (NA) [1]	NA (NA) [1]
CK, Day 42, n=55, 51, 55, 12	-42.3 (342.74)	-18.5 (289.98)	5.5 (67.57)	-17.3 (95.02)
CK, EW, n=2, 2, 0, 0	15.0 (21.21)	33.0 (73.54)	NA (NA) [1]	NA (NA) [1]
GGT, Day 42, n=55, 51, 55, 12	-3.3 (10.65)	-2.5 (6.94)	2.2 (17.24)	3.1 (7.32)
GGT, EW, n=2, 2, 0, 0	-2.5 (6.36)	-0.5 (0.71)	NA (NA) [1]	NA (NA) [1]

[1] Data are not available (missing) for some participants who withdrew from the study early.

18. Secondary Outcome Measure:

Measure Title	Change From Baseline in Albumin and Total Protein Values at Day 42/EW
Measure Description	Blood samples were collected for the measurement of albumin and total protein at Baseline and Day 42/EW. For all laboratory assessments, Baseline is the most recent recorded value at Screening or prior to Day -1/1. Change from Baseline was calculated as the Day 42/EW value minus the Baseline value.

Time Frame	Baseline and Day 42/EW
Safety Issue?	No

Analysis Population Description

ITT Population. Only those participants available at the specified time points were analyzed (represented by n=X, X, X, X in the category titles). Different participants may have been analyzed for different parameters, so the overall number of participants analyzed reflects everyone in the ITT Population.

Reporting Groups

	Description
Placebo	Participants received placebo via a Dry Powder Inhaler (DPI) for 6 weeks, plus a placebo capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation from the DPI once daily at approximately the same time each evening for 6 weeks and to take one placebo capsule each morning on the last 7 days of treatment.
FF/VI 100/25 µg PM	Participants received Fluticasone Furoate/Vilanterol (FF/VI) 100/25 micrograms (µg) via a DPI for 6 weeks, plus a placebo capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation from the DPI once daily at approximately the same time each evening (PM) for 6 weeks and to take one placebo capsule each morning (AM) on the last 7 days of treatment.
FF/VI 200/25 µg PM	Participants received FF/VI 200/25 µg via a DPI for 6 weeks, plus a placebo capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation from the DPI once daily at approximately the same time each evening (PM) for 6 weeks and to take one placebo capsule each morning (AM) on the last 7 days of treatment.
Prednisolone 10 mg AM	Participants received placebo via a DPI for 6 weeks, plus a prednisolone 10 milligram (mg) capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation of placebo from the DPI once daily at approximately the same time each evening (PM) for 6 weeks and to take one Prednisolone capsule each morning (AM) on the last 7 days of treatment.

Measured Values

	Placebo	FF/VI 100/25 µg PM	FF/VI 200/25 µg PM	Prednisolone 10 mg AM
Number of Participants Analyzed	58	56	56	15

	Placebo	FF/VI 100/25 µg PM	FF/VI 200/25 µg PM	Prednisolone 10 mg AM
Change From Baseline in Albumin and Total Protein Values at Day 42/EW [units: Grams per liter] Mean (Standard Deviation)				
Albumin, Day 42, n=55, 51, 55, 12	-2.7 (3.29)	-1.5 (3.02)	-1.3 (3.11)	-0.3 (2.81)
Albumin, EW, n=2, 2, 0, 0	-1.5 (3.54)	0.5 (2.12)	NA (NA) [1]	NA (NA) [1]
Total Protein, Day 42, n=55, 51, 55, 12	-4.1 (5.06)	-1.9 (4.39)	-1.8 (4.65)	-0.8 (4.18)
Total Protein, EW, n=2, 2, 0, 0	-0.5 (3.54)	0.0 (0.00)	NA (NA) [1]	NA (NA) [1]

[1] Data are not available (missing) for some participants who withdrew from the study early.

19. Secondary Outcome Measure:

Measure Title	Change From Baseline in Direct Bilirubin, Indirect Bilirubin, Total Bilirubin, and Creatinine Values at Day 42/EW
Measure Description	Blood samples were collected for the measurement of direct bilirubin, indirect bilirubin, total bilirubin, and creatinine at Baseline and Day 42/EW. For all laboratory assessments, Baseline is the most recent recorded value at Screening or prior to Day -1/1. Change from Baseline was calculated as the Day 42/EW value minus the Baseline value.
Time Frame	Baseline and Day 42/EW
Safety Issue?	No

Analysis Population Description

ITT Population. Only those participants available at the specified time points were analyzed (represented by n=X, X, X, X in the category titles). Different participants may have been analyzed for different parameters, so the overall number of participants analyzed reflects everyone in the ITT Population.

Reporting Groups

	Description
Placebo	Participants received placebo via a Dry Powder Inhaler (DPI) for 6 weeks, plus a placebo capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation from the DPI once daily at approximately the same time each evening for 6 weeks and to take one placebo capsule each morning on the last 7 days of treatment.
FF/VI 100/25 µg PM	Participants received Fluticasone Furoate/Vilanterol (FF/VI) 100/25 micrograms (µg) via a DPI for 6 weeks, plus a placebo capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation from the DPI once daily at approximately the same time each evening (PM) for 6 weeks and to take one placebo capsule each morning (AM) on the last 7 days of treatment.
FF/VI 200/25 µg PM	Participants received FF/VI 200/25 µg via a DPI for 6 weeks, plus a placebo capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation from the DPI once daily at approximately the same time each evening (PM) for 6 weeks and to take one placebo capsule each morning (AM) on the last 7 days of treatment.
Prednisolone 10 mg AM	Participants received placebo via a DPI for 6 weeks, plus a prednisolone 10 milligram (mg) capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation of placebo from the DPI once daily at approximately the same time each evening (PM) for 6 weeks and to take one Prednisolone capsule each morning (AM) on the last 7 days of treatment.

Measured Values

	Placebo	FF/VI 100/25 µg PM	FF/VI 200/25 µg PM	Prednisolone 10 mg AM
Number of Participants Analyzed	58	56	56	15
Change From Baseline in Direct Bilirubin, Indirect Bilirubin, Total Bilirubin, and Creatinine Values at Day 42/EW [units: Micromoles per liter (µmol/L)] Mean (Standard Deviation)				
Direct Bilirubin, Day 42, n=55, 51, 55, 12	-0.6 (1.12)	-0.6 (1.02)	-0.5 (1.10)	0.3 (0.75)
Direct Bilirubin, EW, n=2, 2, 0, 0	-1.0 (0.00)	0.0 (0.00)	NA (NA) [1]	NA (NA) [1]

	Placebo	FF/VI 100/25 µg PM	FF/VI 200/25 µg PM	Prednisolone 10 mg AM
Indirect Bilirubin, Day 42, n=55, 51, 55, 12	-2.0 (4.89)	-2.5 (3.20)	-1.4 (4.72)	-1.0 (2.76)
Indirect Bilirubin, EW, n=2, 2, 0, 0	-1.5 (2.12)	-2.0 (0.00)	NA (NA) [1]	NA (NA) [1]
Total Bilirubin, Day 42, n=55, 51, 55, 12	-2.5 (5.66)	-3.2 (3.72)	-1.8 (5.67)	-0.8 (2.86)
Total Bilirubin, EW, n=2, 2, 0, 0	-2.5 (2.12)	-2.0 (0.00)	NA (NA) [1]	NA (NA) [1]
Creatinine, Day 42, n=55, 51, 55, 12	-0.41 (8.688)	0.35 (8.088)	0.04 (8.052)	4.61 (9.585)
Creatinine, EW, n=2, 2, 0, 0	0.00 (13.435)	0.95 (6.435)	NA (NA) [1]	NA (NA) [1]

[1] Data are not available (missing) for some participants who withdrew from the study early.

20. Secondary Outcome Measure:

Measure Title	Change From Baseline in Chloride, Carbon Dioxide (CO2) Content/Bicarbonate, Glucose, Potassium, Sodium, and Urea/Blood Urea Nitrogen (BUN) Values at Day 42/EW
Measure Description	Blood samples were collected for the measurement of chloride, carbon dioxide (CO2) content/bicarbonate, glucose, potassium, sodium, and urea/blood urea nitrogen (BUN) at Baseline and Day 42/EW. For all laboratory assessments, Baseline is the most recent recorded value at Screening or prior to Day -1/1. Change from Baseline was calculated as the Day 42/EW value minus the Baseline value.
Time Frame	Baseline and Day 42/EW
Safety Issue?	No

Analysis Population Description

ITT Population. Only those participants available at the specified time points were analyzed (represented by n=X, X, X, X in the category titles). Different participants may have been analyzed for different parameters, so the overall number of participants analyzed reflects everyone in the ITT Population.

Reporting Groups

	Description
Placebo	Participants received placebo via a Dry Powder Inhaler (DPI) for 6 weeks, plus a placebo capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation from the DPI once daily at approximately the same time each evening for 6 weeks and to take one placebo capsule each morning on the last 7 days of treatment.
FF/VI 100/25 µg PM	Participants received Fluticasone Furoate/Vilanterol (FF/VI) 100/25 micrograms (µg) via a DPI for 6 weeks, plus a placebo capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation from the DPI once daily at approximately the same time each evening (PM) for 6 weeks and to take one placebo capsule each morning (AM) on the last 7 days of treatment.
FF/VI 200/25 µg PM	Participants received FF/VI 200/25 µg via a DPI for 6 weeks, plus a placebo capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation from the DPI once daily at approximately the same time each evening (PM) for 6 weeks and to take one placebo capsule each morning (AM) on the last 7 days of treatment.
Prednisolone 10 mg AM	Participants received placebo via a DPI for 6 weeks, plus a prednisolone 10 milligram (mg) capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation of placebo from the DPI once daily at approximately the same time each evening (PM) for 6 weeks and to take one Prednisolone capsule each morning (AM) on the last 7 days of treatment.

Measured Values

	Placebo	FF/VI 100/25 µg PM	FF/VI 200/25 µg PM	Prednisolone 10 mg AM
Number of Participants Analyzed	58	56	56	15
Change From Baseline in Chloride, Carbon Dioxide (CO_2) Content/Bicarbonate, Glucose, Potassium, Sodium, and Urea/Blood Urea Nitrogen (BUN) Values at Day 42/EW [units: Millimoles per liter (mmol/L)] Mean (Standard Deviation)				
Chloride, Day 42, n=55, 51, 55, 12	1.2 (2.54)	0.9 (2.76)	0.7 (3.06)	-1.0 (2.41)
Chloride, EW, n=2, 2, 0, 0	2.0 (1.41)	-0.5 (0.71)	NA (NA) [1]	NA (NA) [1]

	Placebo	FF/VI 100/25 µg PM	FF/VI 200/25 µg PM	Prednisolone 10 mg AM
CO2 content/bicarbonate, Day 42, n=54, 50, 51, 12	-1.0 (2.86)	-2.0 (2.98)	-1.5 (2.35)	-0.1 (3.12)
CO2 content/bicarbonate, EW, n=2, 2, 0, 0	-3.5 (2.12)	0.0 (1.41)	NA (NA) [1]	NA (NA) [1]
Glucose, Day 42, n=55, 51, 55, 12	0.11 (1.117)	0.23 (1.037)	-0.03 (0.573)	0.40 (1.397)
Glucose, EW, n=2, 2, 0, 0	1.00 (0.283)	0.40 (0.849)	NA (NA) [1]	NA (NA) [1]
Potassium, Day 42, n=54, 50, 51, 12	-0.10 (0.385)	-0.11 (0.405)	-0.16 (0.379)	0.03 (0.599)
Potassium, EW, n=2, 2, 0, 0	-0.20 (0.283)	-0.65 (0.071)	NA (NA) [1]	NA (NA) [1]
Sodium, Day 42, n=55, 51, 55, 12	0.0 (2.03)	-0.1 (1.98)	-0.1 (3.01)	-0.2 (1.85)
Sodium, EW, n=2, 2, 0, 0	1.5 (3.54)	-3.5 (0.71)	NA (NA) [1]	NA (NA) [1]
Urea/BUN, Day 42, n=55, 51, 55, 12	-0.14 (1.432)	0.48 (1.441)	-0.00 (1.236)	0.94 (1.331)
Urea/BUN, EW, n=2, 2, 0, 0	1.30 (0.283)	-0.85 (0.919)	NA (NA) [1]	NA (NA) [1]

[1] Data are not available (missing) for some participants who withdrew from the study early.

21. Secondary Outcome Measure:

Measure Title	Change From Baseline in Systolic Blood Pressure (SBP) and Diastolic Blood Pressure (DBP) at Days 14, 28, 42, and Maximum Post-Baseline
Measure Description	SBP and DBP were measured at Baseline and at Days 14, 28, 42, and EW. Change from Baseline was calculated as the Day 42/EW value minus the Baseline value. Scheduled, unscheduled, and early withdrawal visits were used for the maximum post-Baseline assessment.
Time Frame	Days 14, 28, 42, and EW
Safety Issue?	No

Analysis Population Description

ITT Population. Only those participants available at the specified time points were analyzed (represented by n=X, X, X, X in the category titles). Different participants may have been analyzed for different parameters, so the overall number of participants analyzed reflects everyone in the ITT Population.

Reporting Groups

	Description
Placebo	Participants received placebo via a Dry Powder Inhaler (DPI) for 6 weeks, plus a placebo capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation from the DPI once daily at approximately the same time each evening for 6 weeks and to take one placebo capsule each morning on the last 7 days of treatment.
FF/VI 100/25 µg PM	Participants received Fluticasone Furoate/Vilanterol (FF/VI) 100/25 micrograms (µg) via a DPI for 6 weeks, plus a placebo capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation from the DPI once daily at approximately the same time each evening (PM) for 6 weeks and to take one placebo capsule each morning (AM) on the last 7 days of treatment.
FF/VI 200/25 µg PM	Participants received FF/VI 200/25 µg via a DPI for 6 weeks, plus a placebo capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation from the DPI once daily at approximately the same time each evening (PM) for 6 weeks and to take one placebo capsule each morning (AM) on the last 7 days of treatment.
Prednisolone 10 mg AM	Participants received placebo via a DPI for 6 weeks, plus a prednisolone 10 milligram (mg) capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation of placebo from the DPI once daily at approximately the same time each evening (PM) for 6 weeks and to take one Prednisolone capsule each morning (AM) on the last 7 days of treatment.

Measured Values

	Placebo	FF/VI 100/25 µg PM	FF/VI 200/25 µg PM	Prednisolone 10 mg AM
Number of Participants Analyzed	58	56	56	15
Change From Baseline in Systolic Blood Pressure (SBP) and Diastolic Blood Pressure (DBP) at Days 14, 28, 42, and Maximum Post-Baseline [units: Millimeters of mercury (mmHg)] Mean (Standard Deviation)				
SBP, Day 14, n=58, 55, 56, 14	-0.5 (11.68)	-1.9 (10.88)	-1.3 (10.53)	-1.0 (13.33)
SBP, Day 28, n=57, 55, 56, 14	-0.9 (9.55)	-0.7 (10.70)	-2.3 (11.66)	-3.9 (13.35)

	Placebo	FF/VI 100/25 µg PM	FF/VI 200/25 µg PM	Prednisolone 10 mg AM
SBP, Day 42, n=55, 54, 56, 13	2.3 (11.96)	-0.4 (12.72)	-1.8 (11.20)	1.5 (8.26)
SBP, maximum post-Baseline, n=58, 56, 56, 15	6.2 (11.44)	5.0 (10.88)	3.9 (10.80)	4.9 (8.61)
DBP, Day 14, n=58, 55, 56, 14	0.0 (7.92)	-1.1 (8.26)	-0.6 (9.08)	0.1 (8.55)
DBP, Day 28, n=57, 55, 56, 14	1.8 (8.38)	-0.6 (7.63)	0.1 (9.97)	-0.4 (8.11)
DBP, Day 42, n=55, 54, 56, 13	1.2 (8.77)	-1.2 (9.13)	0.3 (8.74)	1.2 (8.69)
DBP, maximum post-Baseline, n=58, 56, 56, 15	-3.3 (7.04)	-5.2 (7.76)	-5.4 (9.00)	-4.9 (7.97)

22. Secondary Outcome Measure:

Measure Title	Change From Baseline in Pulse Rate at Days 14, 28, 42, and Maximum Post-Baseline
Measure Description	Heart rate was measured at Baseline and at Days 14, 28, 42, and EW. Change from Baseline was calculated as the Day 42/EW value minus the Baseline value. Scheduled, unscheduled, and early withdrawal visits were used for the maximum post-Baseline assessment.
Time Frame	Days 14, 28, 42, and EW
Safety Issue?	No

Analysis Population Description

ITT Population. Only those participants available at the specified time points were analyzed (represented by n=X, X, X, X in the category titles). Different participants may have been analyzed for different parameters, so the overall number of participants analyzed reflects everyone in the ITT Population.

Reporting Groups

	Description
Placebo	Participants received placebo via a Dry Powder Inhaler (DPI) for 6 weeks, plus a placebo capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation from the DPI once daily at approximately the same time each evening for 6 weeks and to take one placebo capsule each morning on the last 7 days of treatment.

	Description
FF/VI 100/25 µg PM	Participants received Fluticasone Furoate/Vilanterol (FF/VI) 100/25 micrograms (µg) via a DPI for 6 weeks, plus a placebo capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation from the DPI once daily at approximately the same time each evening (PM) for 6 weeks and to take one placebo capsule each morning (AM) on the last 7 days of treatment.
FF/VI 200/25 µg PM	Participants received FF/VI 200/25 µg via a DPI for 6 weeks, plus a placebo capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation from the DPI once daily at approximately the same time each evening (PM) for 6 weeks and to take one placebo capsule each morning (AM) on the last 7 days of treatment.
Prednisolone 10 mg AM	Participants received placebo via a DPI for 6 weeks, plus a prednisolone 10 milligram (mg) capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation of placebo from the DPI once daily at approximately the same time each evening (PM) for 6 weeks and to take one Prednisolone capsule each morning (AM) on the last 7 days of treatment.

Measured Values

	Placebo	FF/VI 100/25 µg PM	FF/VI 200/25 µg PM	Prednisolone 10 mg AM
Number of Participants Analyzed	58	56	56	15
Change From Baseline in Pulse Rate at Days 14, 28, 42, and Maximum Post-Baseline [units: Beats per minute] Mean (Standard Deviation)				
Day 14, n=58, 55, 56, 14	1.5 (13.05)	1.7 (10.70)	0.0 (8.72)	-1.8 (7.92)
Day 28, n=57, 55, 56, 14	2.9 (13.45)	-0.9 (9.32)	-1.9 (12.05)	-2.7 (11.89)
Day 42, n=55, 54, 56, 13	-0.1 (12.65)	-0.9 (11.43)	0.9 (8.96)	-2.3 (9.10)
Maximum post-Baseline, n=58, 56, 56, 15	8.0 (12.47)	6.0 (9.86)	5.5 (8.64)	2.9 (9.13)

Reported Adverse Events

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

Reporting Groups

	Description
Placebo	Participants received placebo via a Dry Powder Inhaler (DPI) for 6 weeks, plus a placebo capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation from the DPI once daily at approximately the same time each evening for 6 weeks and to take one placebo capsule each morning on the last 7 days of treatment.
FF/VI 100/25 µg PM	Participants received Fluticasone Furoate/Vilanterol (FF/VI) 100/25 micrograms (µg) via a DPI for 6 weeks, plus a placebo capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation from the DPI once daily at approximately the same time each evening (PM) for 6 weeks and to take one placebo capsule each morning (AM) on the last 7 days of treatment.
FF/VI 200/25 µg PM	Participants received FF/VI 200/25 µg via a DPI for 6 weeks, plus a placebo capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation from the DPI once daily at approximately the same time each evening (PM) for 6 weeks and to take one placebo capsule each morning (AM) on the last 7 days of treatment.
Prednisolone 10 mg AM	Participants received placebo via a DPI for 6 weeks, plus a prednisolone 10 milligram (mg) capsule on the last 7 days of treatment. Participants were instructed to self-administer one inhalation of placebo from the DPI once daily at approximately the same time each evening (PM) for 6 weeks and to take one Prednisolone capsule each morning (AM) on the last 7 days of treatment.

Serious Adverse Events

	Placebo	FF/VI 100/25 µg PM	FF/VI 200/25 µg PM	Prednisolone 10 mg AM
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	0/58 (0%)	0/56 (0%)	0/56 (0%)	0/15 (0%)

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 3%

	Placebo	FF/VI 100/25 µg PM	FF/VI 200/25 µg PM	Prednisolone 10 mg AM
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	9/58 (15.52%)	20/56 (35.71%)	13/56 (23.21%)	5/15 (33.33%)
Gastrointestinal disorders				
Nausea [A] †	1/58 (1.72%)	0/56 (0%)	0/56 (0%)	1/15 (6.67%)
General disorders				
Fatigue [A] †	0/58 (0%)	0/56 (0%)	0/56 (0%)	1/15 (6.67%)
Infections and infestations				
Nasopharyngitis [A] †	1/58 (1.72%)	2/56 (3.57%)	1/56 (1.79%)	0/15 (0%)
Sinusitis [A] †	0/58 (0%)	2/56 (3.57%)	0/56 (0%)	0/15 (0%)
Musculoskeletal and connective tissue disorders				
Arthralgia [A] †	0/58 (0%)	2/56 (3.57%)	0/56 (0%)	0/15 (0%)
Back pain [A] †	0/58 (0%)	1/56 (1.79%)	2/56 (3.57%)	1/15 (6.67%)
Nervous system disorders				
Dizziness [A] †	0/58 (0%)	0/56 (0%)	0/56 (0%)	1/15 (6.67%)
Facial palsy [A] †	0/58 (0%)	0/56 (0%)	0/56 (0%)	1/15 (6.67%)
Headache [A] †	5/58 (8.62%)	15/56 (26.79%)	9/56 (16.07%)	2/15 (13.33%)
Sinus headache [A] †	0/58 (0%)	1/56 (1.79%)	2/56 (3.57%)	0/15 (0%)
Psychiatric disorders				
Insomnia [A] †	0/58 (0%)	0/56 (0%)	0/56 (0%)	1/15 (6.67%)
Respiratory, thoracic and mediastinal disorders				
Cough [A] †	2/58 (3.45%)	0/56 (0%)	0/56 (0%)	0/15 (0%)

	Placebo	FF/VI 100/25 µg PM	FF/VI 200/25 µg PM	Prednisolone 10 mg AM
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Dyspnoea exertional [A] †	0/58 (0%)	0/56 (0%)	0/56 (0%)	1/15 (6.67%)
Oropharyngeal pain [A] †	2/58 (3.45%)	1/56 (1.79%)	0/56 (0%)	0/15 (0%)
Rhinitis allergic [A] †	0/58 (0%)	2/56 (3.57%)	0/56 (0%)	0/15 (0%)
Vascular disorders				
Hypotension [A] †	0/58 (0%)	0/56 (0%)	0/56 (0%)	1/15 (6.67%)
Varicose vein [A] †	0/58 (0%)	0/56 (0%)	0/56 (0%)	1/15 (6.67%)

† 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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