Protocol Registration Receipt
08/21/2014

Grantor: CBER IND/IDE Number: 077855 050703 Serial Number:

A Study to Evaluate the 24 Hour Spirometric Effect (FEV1) of Fluticasone Furoate/Vilanterol Inhalation Powder (100mcg Fluticasone Furoate (FF)/25mcg Vilanterol (VI)) Compared With Salmeterol/Fluticasone Propionate Inhalation Powder (50mcg Salmeterol/500mcg Fluticasone Propionate (FP))

This study has been completed.

Sponsor:	GlaxoSmithKline
Collaborators:	
Information provided by (Responsible Party):	GlaxoSmithKline
ClinicalTrials.gov Identifier:	NCT01342913

Purpose

The purpose of this study is to evaluate the 24-hour spirometry effect (FEV1) of Fluticasone Furoate/Vilanterol 100/25mcg once daily compared with Salmeterol/Fluticasone Propionate 50/500mcg twice daily over a 12-week treatmen period in subjects with COPD.

Condition	Intervention	Phase
Pulmonary Disease, Chronic Obstructive	Drug: Fluticasone Furoate 100mcg/Vilanterol 25mcg Drug: Fluticaosne Propionate 500mcg/Salmeterol 50mcg	Phase 3

Study Type: Interventional
Study Design: Treatment, Parallel Assignment, Double Blind (Subject, Investigator), Randomized, Safety/Efficacy Study
Official Title: A 12-week Study to Evaluate the 24 Hour Pulmonary Function of Fluticasone Furoate (FF)/Vilanterol Inhalation Powder (FF/VI Inhalation Powder) Once Daily Compared With Salmeterol/Fluticasone Propionate (FP) Inhalation Powder Twice Daily in Subjects With Chronic Obstructive Pulmonary Disease (COPD)

Further study details as provided by GlaxoSmithKline:

Primary Outcome Measure:

- Change From Baseline Trough in 24-hour Weighted-mean FEV1 on Treatment Day 84 [Time Frame: Baseline and Day 84] [Designated as safety issue: No]

  Pulmonary function was measured by forced expiratory volume in one second (FEV1). The weighted mean was calculated from the pre-dose FEV1 and post-dose FEV1 measurements at 5, 15, 30, and 60 minutes (min) and 2, 4, 6, 8, 12, 13, 14, 16, 20, and 24 hours on Treatment Day 84. Baseline trough FEV1 was the mean of the two assessments made 30 and 5 minutes pre-dose on Treatment Day 1. Change from Baseline was calculated as the average of the Day 84 values minus the Baseline value.

Secondary Outcome Measures:

- Time to Onset on Treatment Day 1 [Time Frame: Day 1] [Designated as safety issue: No]

  Time to onset on Treatment Day 1 is defined as the time to an increase of 100 milliliters (mL) from Baseline in FEV1. Time of onset was calculated over 0 to 4 hours (5 min, 15 min, 30 min, 60 min, 120 min, and 240 min) post-dose.
- Change From Baseline in Trough FEV1 on Treatment Day 85 [Time Frame: Baseline and Day 85] [Designated as safety issue: No]

  Pulmonary function was measured by forced expiratory volume in one second (FEV1). Trough FEV1 was defined as the 24-hour FEV1 assessment, which was obtained on Day 85. Baseline is defined as the mean of the two assessments made 30 minutes pre-dose and 5 minutes pre-dose on Treatment Day 1.Change from Baseline was calculated as the average of the Day 85 values minus the Baseline value.

Enrollment: 531
Study Start Date: February 2011
Study Completion Date: October 2011
Primary Completion Date: October 2011

Arms	Assigned Interventions
Experimental: Fluticasone Furoate/Vilanterol Inhaled Corticosteroid (ICS)/Long Acting Beta Agonist (LABA)	Drug: Fluticasone Furoate 100mcg/Vilanterol 25mcg Inhalation Powder
Active Comparator: Fluticasone Propionate/Salmeterol Inhaled Corticosteroid (ICS)/Long Acting Beta Agonist (LABA	Drug: Fluticaosne Propionate 500mcg/Salmeterol 50mcg Inhalation Powder

This is a randomized, double-blind, double-dummy, multi-centre parallel group study. Subjects who meet the eligilibilty criteria at Screening and meet the randomization criteria at the end of a 2-week Run-In period will enter a 12-week Treatment period. There will be a 7-day Follow-up period after the treatment period.

Eligibility

Ages Eligible for Study: 40 Years and older
Genders Eligible for Study: Both

Inclusion Criteria:

- Signed and dated written informed consent
- Male or females ≥ 40 years of age
- Established clinical history of COPD by ATS/ERS definition
- Females are eligible to enter and participate if of non-childbearing potential, or if of child bearing potential, has a negative serum pregnancy test at screening, and agrees to one of the acceptable contraceptive methods listed in protocol, used consistently and correctly
- Former or current smoker > 10 pack years
- Post-albuterol spirometry criteria: FEV1/FVC ratio ≤ 0.70 and FEV1 ≤ 70% of predicted normal (NHANES III)
- have been hospitalised or have been treated with oral corticosteroids or antibiotics for their COPD within the last 3 years prior to Screening (Visit 1)

Exclusion Criteria:

- Current diagnosis of asthma
- Subjects with other respiratory disorders including active tuberculosis, α1-antitrypsin deficiency, lung cancer, bronchiectasis, sarcoidosis, lung fibrosis,

pulmonary hypertension, interstitial lung diseases or other active pulmonary diseases
- Lung volume reduction surgery within previous 12 months
- Clinically significant abnormalities not due to COPD by chest x-ray
- Hospitalized for poorly controlled COPD within 12 weeks of Screening
- Poorly controlled COPD 6 weeks prior to Screening, defined as acute worsening of COPD that is managed by the subject with corticosteroids or antibiotics or that requires treatment prescribed by a physician
- Lower respiratory infection requiring antibiotics 6 weeks prior to Screening
- Uncontrolled or clinically significant (in opinion of PI) cardiovascular, hypertension, neurological, psychiatric, renal, hepatic, immunological, endocrine, peptic ulcer disease, or hematological abnormalities
- Carcinoma not in complete remission for at least 5 years
- Subjects with history of hypersensitivity to study medications (e.g., beta-agonists, corticosteroid) or components of inhalation powder (e.g., lactose, magnesium stearate)
- Subjects with history of severe milk protein allergy that, in opinion of study physician, contraindicates subject’s participation - Known/suspected history of alcohol or drug abuse in the last 2 years
- Women who are pregnant or lactating or plan to become pregnant
- Subjects medically unable to withhold albuterol and/or ipratropium 4 hours prior to spirometry testing at each study visit
- Use of certain medications such as bronchodilators and corticosteroids for the protocol-specific times prior to Visit 1 (the Investigator will discuss the specific medications)
- Long Term Oxygen Therapy (LTOT) or nocturnal oxygen therapy >12 hours a day
- Participation in the acute phase of a pulmonary rehabilitation program within 4 weeks prior to Screening or during the study - Non-compliance or inability to comply with study procedures or scheduled visits
- Affiliation with investigator site

Contacts and Locations

Locations

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Investigators

Study Director:	GSK Clinical Trials	GlaxoSmithKline

More Information

Responsible Party: GlaxoSmithKline
Study ID Numbers: 113107
Health Authority: United States: Food and Drug Administration
Europe: European Medicines Agency

Study Results

Participant Flow

Pre-Assignment Details

At Visit 1, participants entered a 2-week, single-blind (placebo) Run-in Period to obtain Baseline assessments of salbutamol use and to evaluate adherence with study treatment and procedures, diary card completion, and assessment of disease stability. At Visit 2, participants were randomized to a 12-week, double-blind Treatment Period.

Reporting Groups

	Description
Placebo + Salbutamol	Participants were instructed to take single-blind placebo (ACCUHALER/DISKUS and Novel Dry Powder Inhaler [NDPI]): one inhalation each morning from each device, and one inhalation from the ACCUHALER/DISKUS in the evening. In addition, all participants received supplemental albuterol (salbutamol) (metered dose inhaler [MDI] and/or nebules) to be used on an as-needed basis. Ipratropium bromide alone was permitted, provided that the participant was on a stable dose from Visit 1 (Screening) and remained on the stable dose throughout the study; however, ipratropium must have been withheld for 4 hours prior to and during each clinic visit.
Salmeterol/FP 50/500 µg BID	Participants received a Salmeterol and Fluticasone Propionate (FP) 50/500 microgram (µg) inhalation (available as a combination dry

	Description
	inhalation powder of Salmeterol 50 µg and FP 500 µg in single strip) twice daily (BID) (morning and evening) from the ACCUHALER/DISKUS and placebo once daily (QD) in the morning from the NDPI over the course of 12 weeks.
FF/VI 100/25 µg QD	Participants received a Fluticasone Furoate /Vilanterol (FF/VI) 100/25 µg inhalation (available as dry inhalation powder in two separate strips of FF 100 µg and VI 25 µg) QD in the morning from the NDPI and placebo BID (morning and evening) from the ACCUHALER/DISKUS over the course of 12 weeks.

2-week Run-in Period

	Placebo + Salbutamol	Salmeterol/FP 50/500 µg BID	FF/VI 100/25 µg QD
Started	702	0	0
Completed	528	0	0
Not Completed	174	0	0
Inclusion/Exclusion Criteria Not Met	66	0	0
Physician Decision	6	0	0
Withdrawal by Subject	7	0	0
Adverse Event	2	0	0
Protocol Violation	5	0	0
Continuation Criteria Not Met	88	0	0

Double-Blind Treatment Period

	Placebo + Salbutamol	Salmeterol/FP 50/500 µg BID	FF/VI 100/25 µg QD
Started	0	262	266
Completed	0	246	243
Not Completed	0	16	23
Adverse Event	0	3	6
Lack of Efficacy	0	2	3
Protocol Violation	0	6	9
Lost to Follow-up	0	1	3
Physician Decision	0	2	0
Withdrawal by Subject	0	2	2

Baseline Characteristics

Reporting Groups

	Description
Salmeterol/FP 50/500 µg BID	Participants received a Salmeterol and Fluticasone Propionate (FP) 50/500 microgram (µg) inhalation (available as a combination dry inhalation powder of Salmeterol 50 µg and FP 500 µg in single strip) twice daily (BID) (morning and evening) from the ACCUHALER/DISKUS and placebo once daily (QD) in the morning from the NDPI over the course of 12 weeks.
FF/VI 100/25 µg QD	Participants received a Fluticasone Furoate /Vilanterol (FF/VI) 100/25 µg inhalation (available as dry inhalation powder in two separate strips

	Description
	of FF 100 µg and VI 25 µg) QD in the morning from the NDPI and placebo BID (morning and evening) from the ACCUHALER/DISKUS over the course of 12 weeks.

Baseline Measures

	Salmeterol/FP 50/500 µg BID	FF/VI 100/25 µg QD	Total
Number of Participants	262	266	528
Age, Continuous [units: Years] Mean (Standard Deviation)	62.9 (9.07)	63.0 (8.10)	62.9 (8.59)
Gender, Male/Female [units: Participants]			
Female	41	54	95
Male	221	212	433
Race/Ethnicity, Customized [units: participants]			
African American/African Heritage	1	0	1
Asian-South East Asian Heritage	53	48	101
White-Arabic/North African Hertage	2	1	3
White/Caucasian/European Heritage	206	217	423

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Change From Baseline Trough in 24-hour Weighted-mean FEV1 on Treatment Day 84
Measure Description	Pulmonary function was measured by forced expiratory volume in one second (FEV1). The weighted mean was calculated from the pre-dose FEV1 and post-dose FEV1 measurements at 5, 15, 30, and 60 minutes (min) and 2, 4, 6, 8, 12, 13, 14, 16, 20, and 24 hours on Treatment Day 84. Baseline trough FEV1 was the mean of the two assessments made 30 and 5 minutes pre-dose on Treatment Day 1. Change from Baseline was calculated as the average of the Day 84 values minus the Baseline value.
Time Frame	Baseline and Day 84
Safety Issue?	No

Analysis Population Description

Intent-to-Treat (ITT) Population: all participants randomized to treatment who received at least 1 dose of double-blind medication. Randomized participants were assumed to have received double-blind medication unless definitive evidence to the contrary existed. Only participants available at the indicated time point were assessed.

Reporting Groups

	Description
Salmeterol/FP 50/500 µg BID	Participants received a Salmeterol and Fluticasone Propionate (FP) 50/500 microgram (µg) inhalation (available as a combination dry inhalation powder of Salmeterol 50 µg and FP 500 µg in single strip) twice daily (BID) (morning and evening) from the ACCUHALER/DISKUS and placebo once daily (QD) in the morning from the NDPI over the course of 12 weeks.

	Description
FF/VI 100/25 µg QD	Participants received a Fluticasone Furoate /Vilanterol (FF/VI) 100/25 µg inhalation (available as dry inhalation powder in two separate strips of FF 100 µg and VI 25 µg) QD in the morning from the NDPI and placebo BID (morning and evening) from the ACCUHALER/DISKUS over the course of 12 weeks.

Measured Values

	Salmeterol/FP 50/500 µg BID	FF/VI 100/25 µg QD
Number of Participants Analyzed	233	224
Change From Baseline Trough in 24-hour Weighted-mean FEV1 on Treatment Day 84 [units: Liters] Least Squares Mean (Standard Error)	0.108 (0.0145)	0.130 (0.0148)

Statistical Analysis 1 for Change From Baseline Trough in 24-hour Weighted-mean FEV1 on Treatment Day 84

Groups	Salmeterol/FP 50/500 µg BID, FF/VI 100/25 µg QD
Method	ANCOVA
P-Value	0.282
Other Estimated Parameter [Least squares mean difference]	0.022
95% Confidence Interval	-0.018 to 0.063

Additional details about the analysis, such as null hypothesis and power calculation:

[Not specified.]

Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for

statistical significance:

[Not specified.]

Other relevant information, such as adjustments or degrees of freedom:

[Not specified.]

2. Secondary Outcome Measure:

Measure Title	Time to Onset on Treatment Day 1
Measure Description	Time to onset on Treatment Day 1 is defined as the time to an increase of 100 milliliters (mL) from Baseline in FEV1. Time of onset was calculated over 0 to 4 hours (5 min, 15 min, 30 min, 60 min, 120 min, and 240 min) post-dose.
Time Frame	Day 1
Safety Issue?	No

Analysis Population Description

ITT Population. Only participants available at the indicated time point were assessed.

Reporting Groups

	Description
Salmeterol/FP 50/500 µg BID	Participants received a Salmeterol and Fluticasone Propionate (FP) 50/500 microgram (µg) inhalation (available as a combination dry inhalation powder of Salmeterol 50 µg and FP 500 µg in single strip) twice daily (BID) (morning and evening) from the ACCUHALER/DISKUS and placebo once daily (QD) in the morning from the NDPI over the course of 12 weeks.
FF/VI 100/25 µg QD	Participants received a Fluticasone Furoate /Vilanterol (FF/VI) 100/25 µg inhalation (available as dry inhalation powder in two separate strips of FF 100 µg and VI 25 µg) QD in the morning from the NDPI and placebo BID (morning and evening) from the ACCUHALER/DISKUS

	Description
	over the course of 12 weeks.

Measured Values

	Salmeterol/FP 50/500 µg BID	FF/VI 100/25 µg QD
Number of Participants Analyzed	260	260
Time to Onset on Treatment Day 1 [units: Minutes] Median (Full Range)	28 (5 to 240)	16 (5 to 240)

3. Secondary Outcome Measure:

Measure Title	Change From Baseline in Trough FEV1 on Treatment Day 85
Measure Description	Pulmonary function was measured by forced expiratory volume in one second (FEV1). Trough FEV1 was defined as the 24-hour FEV1 assessment, which was obtained on Day 85. Baseline is defined as the mean of the two assessments made 30 minutes pre-dose and 5 minutes pre-dose on Treatment Day 1.Change from Baseline was calculated as the average of the Day 85 values minus the Baseline value.
Time Frame	Baseline and Day 85
Safety Issue?	No

Analysis Population Description

Only participants available at the indicated time point were assessed.

Reporting Groups

	Description
Salmeterol/FP 50/500 µg BID	Participants received a Salmeterol and Fluticasone Propionate (FP) 50/500 microgram (µg) inhalation (available as a combination dry inhalation powder of Salmeterol 50 µg and FP 500 µg in single strip) twice daily (BID) (morning and evening) from the ACCUHALER/DISKUS and placebo once daily (QD) in the morning from the NDPI over the course of 12 weeks.
FF/VI 100/25 µg QD	Participants received a Fluticasone Furoate /Vilanterol (FF/VI) 100/25 µg inhalation (available as dry inhalation powder in two separate strips of FF 100 µg and VI 25 µg) QD in the morning from the NDPI and placebo BID (morning and evening) from the ACCUHALER/DISKUS over the course of 12 weeks.

Measured Values

	Salmeterol/FP 50/500 µg BID	FF/VI 100/25 µg QD
Number of Participants Analyzed	245	242
Change From Baseline in Trough FEV1 on Treatment Day 85 [units: Liters] Least Squares Mean (Standard Error)	0.088 (0.0154)	0.111 (0.0155)

Reported Adverse Events

Reporting Groups

	Description
Salmeterol/FP 50/500 µg BID	Participants received a Salmeterol and Fluticasone Propionate (FP)

	Description
	50/500 microgram (µg) inhalation (available as a combination dry inhalation powder of Salmeterol 50 µg and FP 500 µg in single strip) twice daily (BID) (morning and evening) from the ACCUHALER/DISKUS and placebo once daily (QD) in the morning from the NDPI over the course of 12 weeks.
FF/VI 100/25 µg QD	Participants received a Fluticasone Furoate /Vilanterol (FF/VI) 100/25 µg inhalation (available as dry inhalation powder in two separate strips of FF 100 µg and VI 25 µg) QD in the morning from the NDPI and placebo BID (morning and evening) from the ACCUHALER/DISKUS over the course of 12 weeks.

Time Frame

Serious adverse events (SAEs) and non-serious AEs were collected from the start of study medication until Follow-up (up to 12 weeks).

Additional Description

All AEs and SAEs were followed until resolution, until the condition stabilized, until the event was otherwise explained, or until the participant was lost to follow-up.

Serious Adverse Events

	Salmeterol/FP 50/500 µg BID	FF/VI 100/25 µg QD
Total # participants affected/at risk	3/262 (1.15%)	6/266 (2.26%)
Cardiac disorders		
Angina pectoris †[A]		
# participants affected/at risk	0/262 (0%)	1/266 (0.38%)

	Salmeterol/FP 50/500 µg BID	FF/VI 100/25 µg QD
# events		
Atrial fibrillation † [A]		
# participants affected/at risk	0/262 (0%)	2/266 (0.75%)
# events		
Coronary artery disease † [A]		
# participants affected/at risk	0/262 (0%)	1/266 (0.38%)
# events		
Gastrointestinal disorders		
Food poisoning † [A]		
# participants affected/at risk	0/262 (0%)	1/266 (0.38%)
# events		
Infections and infestations		
Infective exacerbation of chronic obstructive airways diseas † [A]		
# participants affected/at risk	0/262 (0%)	1/266 (0.38%)

	Salmeterol/FP 50/500 µg BID	FF/VI 100/25 µg QD
# events		
Pneumonia † [A]		
# participants affected/at risk	2/262 (0.76%)	1/266 (0.38%)
# events		
Sialoadenitis † [A]		
# participants affected/at risk	1/262 (0.38%)	0/266 (0%)
# events		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Rectal cancer † [A]		
# participants affected/at risk	0/262 (0%)	1/266 (0.38%)
# events		
Respiratory, thoracic and mediastinal disorders		
Chronic obstructive pulmonary disease † [A]		
# participants affected/at risk	0/262 (0%)	1/266 (0.38%)

	Salmeterol/FP 50/500 µg BID	FF/VI 100/25 µg QD
# events		

† Indicates events were collected by systematic assessment.

A Term from vocabulary, MedDRA

Other Adverse Events

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

	Salmeterol/FP 50/500 µg BID	FF/VI 100/25 µg QD
Total # participants affected/at risk	30/262 (11.45%)	32/266 (12.03%)
Infections and infestations		
Nasopharyngitis † [A]		
# participants affected/at risk	12/262 (4.58%)	8/266 (3.01%)
# events		
Musculoskeletal and connective tissue disorders		
Back pain † [A]		
# participants affected/at risk	3/262 (1.15%)	10/266 (3.76%)
# events		

	Salmeterol/FP 50/500 µg BID	FF/VI 100/25 µg QD
Nervous system disorders		
Headache † [A]		
# participants affected/at risk	18/262 (6.87%)	20/266 (7.52%)
# events		

† Indicates events were collected by systematic assessment.

A Term from vocabulary, MedDRA

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.

Limitations and Caveats:

Results Point of Contact:

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