ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: January 8, 2018

ClinicalTrials.gov ID: NCT00858286

Study Identification

Unique Protocol ID:	109780
Brief Title:	A Follow-up Survey to Compare Stable Dosing (SERETIDE) With SYMBICORT, SMART, Maintenance and Reliever Therapy in One Inhaler in Moderate and Severe Asthmatics.
Official Title:	Follow-up Survey to Compare Stable Dosing (SERETIDE) With SYMBICORT SMART, Maintenance and Reliever Therapy in One Inhaler in Moderate and Severe Asthmatics.
Secondary IDs:	

Study Status

Record Verification:	July 2017
Overall Status:	Completed
Study Start:	February 9, 2009 []
Primary Completion:	April 1, 2010 [Actual]
Study Completion:	April 22, 2010 [Actual]

Sponsor/Collaborators

Sponsor:	GlaxoSmithKline
Responsible Party:	Sponsor
Collaborators:	

Oversight

U.S. FDA-regulated Drug:	

U.S. FDA-regulated Device:	
U.S. FDA IND/IDE:	No
Human Subjects Review:	Board Status: Approved Approval Number: 2008/1529-31 Board Name: Regionala Etikprövningsnämnden i Stockholm Board Affiliation: Karolinska Institutet Phone: + 46 8 5248 6472 Email: kansli@stockholm.epn.se Address: Karolinska Institutet, Nobels väg 12 A, SE-171 77 STOCKHOLM
Data Monitoring:	No
FDA Regulated Intervention:	No

Study Description

Brief Summary:	The purpose with this study is to describe in detail the control or lack of control of asthma, based on two different dosing strategies, regular treatment with SERETIDE in a stable dosing with short acting beta-2 agonists as needed, or maintenance treatment with SYMBICORT and using the same inhaler with SYMBICORT as needed.
Detailed Description:	The purpose with this study is to describe in detail the control or lack of control of asthma, based on two different dosing strategies. No therapy intervention is made with existing prescribed medications (SERETIDE or SYMBICORT), but evaluations outside standard care is made by evluations with diary cards, questionnaires, PEF evaluations and spirometry which is regarded as the intervention by the Swedish Authorities.

Conditions

Conditions:	Asthma
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 4
Interventional Study Model:	Parallel Assignment
Number of Arms:	2

Masking:	None (Open Label)
Allocation:	Non-Randomized
Enrollment:	56 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Stable dosing with SERETIDE, short acting B-2agonist as needed Regular treatment with SERETIDE in a stable dosing with short acting beta-2 agonists as needed	Spirometry, PEF measurements and diary cards to evaluate control of Asthma No intervention is made with the existing therapy, but patient will perform spirometry and PEF evaluations together with a registration of control of asthma in diary cards and health economic parameters in questionnaires
Experimental: Maintenance treatment with SYMBICORT and SYMBICORT as needed Maintenance treatment with SYMBICORT and using the same inhaler with SYMBICORT as needed	Spirometry, PEF measurements and diary cards to evaluate control of Asthma No intervention is made with the existing therapy, but patient will perform spirometry and PEF evaluations together with a registration of control of asthma in diary cards and health economic parameters in questionnaires

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age:	18 Years
Maximum Age:	
Sex:	All
Gender Based:	
Accepts Healthy Volunteers:	No
Criteria:	Inclusion Criteria:

- written informed consent
- 18 years or above
- able to fill in questionnaires and perform PEF measurements
- asthma diagnosis and prescribed SERETIDE or SYMBICORT, either regular treatment using SERETIDE in a stable dosing and short acting B2 agonists as needed, or maintenance treatment with SYMBICORT but also using same inhaler SYMBICORT as needed

Exclusion Criteria:

- no other lung disease
- neurological disease with psychological handicap
- cerebro-vascular disease with handicap
- un-stable cancer
- known or planned pregnancy during the time of the study
- subjects who have serious uncontrolled disease

Contacts/Locations

Central Contact Person: US GSK Clinical Trials Call Center
Telephone: 877-379-3718
Email: GSKClinicalSupportHD@gsk.com

Central Contact Backup:

Study Officials: GSK Clinical Trials
Study Director
GlaxoSmithKline

Locations: Sweden
GSK Investigational Site
STOCKHOLM, Sweden, SE-171 77
Contact: US GSK Clinical Trials Call Center 877-379-3718 GSKClinicalSupportHD@gsk.com
Contact: EU GSK Clinical Trials Call Center +44 (0) 20 8990 4466 GSKClinicalSupportHD@gsk.com

IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information:

Study Results

Participant Flow

Recruitment Details	The study was conducted in moderate and severe persistent asthma participants, from 09 February 2009 to 22 April 2010 at a single center in Sweden.

Reporting Groups

	Description
Salmeterol/Fluticasone	No intervention was administered. This was an observational study, to study the effect of dosing strategy of Salmeterol/fluticasone, as prescribed.
Budesonide/Formoterol	No intervention was administered. This was an observational study, to study the effect of dosing strategy of budesonide/formoterol, as prescribed.

Overall Study

	Salmeterol/Fluticasone	Budesonide/Formoterol
Started	18	38
Completed	18	15
Not Completed	0	23
Unknown	0	23

Baseline Characteristics

Reporting Groups

	Description
Salmeterol/Fluticasone	No intervention was administered. This was an observational study, to study the effect of dosing strategy of Salmeterol/fluticasone, as prescribed.
Budesonide/Formoterol	No intervention was administered. This was an observational study, to study the effect of dosing strategy of budesonide/formoterol, as prescribed.

Baseline Measures

	Salmeterol/Fluticasone	Budesonide/Formoterol	Total
Overall Number of Participants	18	38	56

		Salmeterol/Fluticasone	Budesonide/Formoterol	Total
Age, Customized Measure Type: Count of Participants Unit of measure: Participants	Number Analyzed	18 participants	38 participants	56 participants
> 18 years		18 100%	38 100%	56 100%
Sex/Gender, Customized Measure Type: Count of Participants Unit of measure: Participants	Number Analyzed	18 participants	38 participants	56 participants
Missing		18 100%	38 100%	56 100%

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Asthma Control Based on Revised Global Initiative for Asthma (GINA) Guidelines From 2007
Measure Description	This evaluated the number of participants who were well controlled, partly controlled or uncontrolled asthmatics, using the asthma control based on GINA guidelines from 2007, which contained the details for management and prevention of asthma. This data was not collected.
Time Frame	Up to 3 months

Analysis Population Description

All Subject Population, was defined as participants who received atleast one dose of study drug. Data was not collected for this outcome measure.

Reporting Groups

	Description
Salmeterol/Fluticasone	No intervention was administered. This was an observational study, to study the effect of dosing strategy of Salmeterol/fluticasone, as prescribed.
Budesonide/Formoterol	No intervention was administered. This was an observational study, to study the effect of dosing strategy of budesonide/formoterol, as prescribed.

Measured Values

	Salmeterol/Fluticasone	Budesonide/Formoterol
Overall Number of Participants Analyzed	0	0

No data displayed because Outcome Measure has zero total participants analyzed.

2. Secondary Outcome Measure:

Measure Title	Asthma Day and Night Symptoms
Measure Description	During the treatment the participants were asked to record the symptoms (cold, wheeze, chest tightness etc), in a participant diary, experienced during the day or night. This accounted for the number of days where activities were affected or the nights (sleep disturbance). A scale used was the daily scale where 0= No symptoms, 1= Mild symptoms, 2= moderate symptoms and 3= severe symptoms. Data not collected.
Time Frame	Up to 3 months

Analysis Population Description

All Subject population. Data was not collected for this outcome measure.

Reporting Groups

	Description
Salmeterol/Fluticasone	No intervention was administered. This was an observational study, to study the effect of dosing strategy of Salmeterol/fluticasone, as prescribed.
Budesonide/Formoterol	No intervention was administered. This was an observational study, to study the effect of dosing strategy of budesonide/formoterol, as prescribed.

Measured Values

	Salmeterol/Fluticasone	Budesonide/Formoterol
Overall Number of Participants Analyzed	0	0

No data displayed because Outcome Measure has zero total participants analyzed.

3. Secondary Outcome Measure:

Measure Title	Morning and Evening Peak Flow
Measure Description	This were performed daily, in morning upon arising before taking medication and in evening. The best of the 3 were recorded. Data not collected
Time Frame	Up to 3 months

Analysis Population Description

All Subject population. Data was not collected for this outcome measure.

Reporting Groups

	Description
Salmeterol/Fluticasone	No intervention was administered. This was an observational study, to study the effect of dosing strategy of Salmeterol/fluticasone, as prescribed.
Budesonide/Formoterol	No intervention was administered. This was an observational study, to study the effect of dosing strategy of budesonide/formoterol, as prescribed.

Measured Values

	Salmeterol/Fluticasone	Budesonide/Formoterol
Overall Number of Participants Analyzed	0	0

No data displayed because Outcome Measure has zero total participants analyzed.

4. Secondary Outcome Measure:

Measure Title	Use of Day and Night Rescue Medication
Measure Description	The total amount of rescue medications used, during the treatment period, calculated by the sum used during Day and night was to be measured. However this data was not collected.
Time Frame	Up to 3 months

Analysis Population Description

All Subject population. Data was not collected for this outcome measure

Reporting Groups

	Description
Salmeterol/Fluticasone	No intervention was administered. This was an observational study, to study the effect of dosing strategy of Salmeterol/fluticasone, as prescribed.
Budesonide/Formoterol	No intervention was administered. This was an observational study, to study the effect of dosing strategy of budesonide/formoterol, as prescribed.

Measured Values

	Salmeterol/Fluticasone	Budesonide/Formoterol
Overall Number of Participants Analyzed	0	0

No data displayed because Outcome Measure has zero total participants analyzed.

5. Secondary Outcome Measure:

Measure Title	Asthma Exacerbations
Measure Description	Asthma exacerbation was defined as a participant having one of the following: 1. Increase in the Asthma Control Questionnaire (ACQ) from Baseline to the end of treatment period by 0.5 or more.. The ACQ is a validated instrument containing 7 questions to assess asthma control which incorporates symptoms, beta-agonist use, and spirometry. Participants recall their experiences during the previous 7 days and respond to each question using a 7-point scale. The items are equally weighted and the ACQ score is the mean of the 7 items and therefore ranges between 0 (well controlled) and 6 (extremely poorly controlled). The ACQ completed on the day of exposure was the Baseline ACQ. 2. Any change to asthma treatment as prescribed by a physician, unscheduled contact (either office visit or phone contact where medication was changed for asthma symptoms), emergency room visit, or hospitalization. Data not collected.
Time Frame	Up to 3 months

Analysis Population Description

All Subject population. Data was not collected for this outcome measure.

Reporting Groups

	Description
Salmeterol/Fluticasone	No intervention was administered. This was an observational study, to study the effect of dosing strategy of Salmeterol/fluticasone, as prescribed.
Budesonide/Formoterol	No intervention was administered. This was an observational study, to study the effect of dosing strategy of budesonide/formoterol, as prescribed.

Measured Values

	Salmeterol/Fluticasone	Budesonide/Formoterol
Overall Number of Participants Analyzed	0	0

No data displayed because Outcome Measure has zero total participants analyzed.

6. Secondary Outcome Measure:

Measure Title	Quality of Life According to the Generic SF-36 Questionnaire
Measure Description	This is a self-administered a general health status questionnaire made of 36 questions, measuring 8 health concepts as physical/emotional function, role function, pain, perception of general health, vitality, mental/physical health, and social functioning measured on a scale of 0 to 100. The score for a particular component is an average of individual question score. Here 0=worst health-related quality of life and 100=best health related quality of life. Thus a higher score was indicative of more favorable health status. Data not collected.
Time Frame	Up to 3 months

Analysis Population Description

All Subject population. Data was not collected for this outcome measure.

Reporting Groups

	Description
Salmeterol/Fluticasone	No intervention was administered. This was an observational study, to study the effect of dosing strategy of Salmeterol/fluticasone, as prescribed.
Budesonide/Formoterol	No intervention was administered. This was an observational study, to study the effect of dosing strategy of budesonide/formoterol, as prescribed.

Measured Values

	Salmeterol/Fluticasone	Budesonide/Formoterol
Overall Number of Participants Analyzed	0	0

No data displayed because Outcome Measure has zero total participants analyzed.

7. Secondary Outcome Measure:

Measure Title	Quality of Life According to the Disease Specific Juniper-Guyatt Questionnaire
Measure Description	This has 7 questions (the top scoring 5 symptoms, Forced expiratory volume in 1 second (FEV1) % predose and daily rescue bronchodilator use). Participants were asked to recall how their asthma had been during the previous week and to respond to the symptom and bronchodilator use questions on a 7-point scale (0=no impairment, 6= maximum impairment). Clinic staff score the FEV1% predicted on a 7-point scale. The questions are equally weighted and the ACQ score is the mean of the 7 questions and therefore between 0 (totally controlled) and 6 (severely uncontrolled). This data was not collected.
Time Frame	Up to 3 months

Analysis Population Description

All Subject population. Data was not collected for this outcome measure.

Reporting Groups

	Description
Salmeterol/Fluticasone	No intervention was administered. This was an observational study, to study the effect of dosing strategy of Salmeterol/fluticasone, as prescribed.
Budesonide/Formoterol	No intervention was administered. This was an observational study, to study the effect of dosing strategy of budesonide/formoterol, as prescribed.

Measured Values

	Salmeterol/Fluticasone	Budesonide/Formoterol
Overall Number of Participants Analyzed	0	0

No data displayed because Outcome Measure has zero total participants analyzed.

8. Secondary Outcome Measure:

Measure Title	All Health Related Contacts, Total and by Grade of Severity, i.e. Hospitalizations, Phone Contacts Etc.
Measure Description	The contacts made during the study to the participant to enquire about the health of the participant, the grade of severity (mild, moderate, severe), hospitalizations for the participant if any, and the number of phone contacts made by the participant. However this data was not collected.
Time Frame	Up to 3 months

Analysis Population Description

All Subject population. Data was not collected for this outcome measure.

Reporting Groups

	Description
Salmeterol/Fluticasone	No intervention was administered. This was an observational study, to study the effect of dosing strategy of Salmeterol/fluticasone, as prescribed.
Budesonide/Formoterol	No intervention was administered. This was an observational study, to study the effect of dosing strategy of budesonide/formoterol, as prescribed.

Measured Values

	Salmeterol/Fluticasone	Budesonide/Formoterol
Overall Number of Participants Analyzed	0	0

No data displayed because Outcome Measure has zero total participants analyzed.

9. Secondary Outcome Measure:

Measure Title	Sick Leave in Both Days and Part of Days
Measure Description	The number of days sick leaves taken, as either for a full day or part of the day were to be recorded. However this data was not collected.
Time Frame	Up to 3 months

Analysis Population Description
All Subject population. Data was not collected for this outcome measure.

Reporting Groups

	Description
Salmeterol/Fluticasone	No intervention was administered. This was an observational study, to study the effect of dosing strategy of Salmeterol/fluticasone, as prescribed.
Budesonide/Formoterol	No intervention was administered. This was an observational study, to study the effect of dosing strategy of budesonide/formoterol, as prescribed.

Measured Values

	Salmeterol/Fluticasone	Budesonide/Formoterol
Overall Number of Participants Analyzed	0	0

No data displayed because Outcome Measure has zero total participants analyzed.

10. Secondary Outcome Measure:

Measure Title	Asthma Related Direct and Indirect Costs
Measure Description	The relative costs linked to asthma directly or indirectly were evaluated. This data was not collected.
Time Frame	Up to 3 months

Analysis Population Description
All Subject population. Data was not collected for this outcome measure.

Reporting Groups

	Description
Salmeterol/Fluticasone	No intervention was administered. This was an observational study, to study the effect of dosing strategy of Salmeterol/fluticasone, as prescribed.
Budesonide/Formoterol	No intervention was administered. This was an observational study, to study the effect of dosing strategy of budesonide/formoterol, as prescribed.

Measured Values

	Salmeterol/Fluticasone	Budesonide/Formoterol
Overall Number of Participants Analyzed	0	0

No data displayed because Outcome Measure has zero total participants analyzed.

Reported Adverse Events

Time Frame	Up to 3 months
Adverse Event Reporting Description	The data for all serious adverse events and non-serious adverse events was collected.

Reporting Groups

	Description
Salmeterol/Fluticasone	No intervention was administered. This was an observational study, to study the effect of dosing strategy of Salmeterol/fluticasone, as prescribed.
Budesonide/Formoterol	No intervention was administered. This was an observational study, to study the effect of dosing strategy of budesonide/formoterol, as prescribed.

All-Cause Mortality

	Salmeterol/Fluticasone	Budesonide/Formoterol
	Affected/At Risk (%)	Affected/At Risk (%)
Total All-Cause Mortality	0/18 (0%)	0/38 (0%)

Serious Adverse Events

	Salmeterol/Fluticasone	Budesonide/Formoterol
	Affected/At Risk (%)	Affected/At Risk (%)
Total	1/18 (5.56%)	2/38 (5.26%)
Gastrointestinal disorders		
Cholecystitis [A] †	0/18 (0%)	1/38 (2.63%)
Stomach ulcer [A] †	0/18 (0%)	1/38 (2.63%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Breast cancer [A] †	1/18 (5.56%)	0/38 (0%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA 12.1

Other Adverse Events

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

	Salmeterol/Fluticasone	Budesonide/Formoterol
	Affected/At Risk (%)	Affected/At Risk (%)
Total	9/18 (50%)	7/38 (18.42%)
Infections and infestations		
Upper respiratory tract infection [A] †	9/18 (50%)	7/38 (18.42%)

† Indicates events were collected by systematic assessment.

A Term from vocabulary, MedDRA 12.1

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.

Results Point of Contact:

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