ClinicalTrials.gov Protocol and Results Registration System (PRS) Receipt
Release Date: 07/27/2012

ClinicalTrials.gov ID: NCT00542880

Study Identification

Unique Protocol ID:	D5892C00016
Brief Title:	Evaluation of Onset of Effect in Patients With Severe Chronic Obstructive Pulmonary Disease (COPD) Treated With Symbicort® Compared to Seretide® (SPEED)
Official Title:	A Double-blind, Randomised, Cross-over, Multi-centre Study, to Evaluate Onset of Effect in the Morning in Patients With Severe Chronic Obstructive Pulmonary Disease (COPD) Treated With Symbicort®Turbuhaler® 320/9 µg, Compared With Seretide® Diskus® 50/500 µg, Both Given as One Inhalation Twice Daily for One Week Each.
Secondary IDs:	

Study Status

Record Verification:	July 2012
Overall Status:	Completed
Study Start:	September 2007
Primary Completion:	August 2008 [Actual]
Study Completion:	August 2008 [Actual]

Sponsor/Collaborators

Sponsor:	AstraZeneca
Responsible Party:	Sponsor
Collaborators:	

Oversight

FDA Regulated?:	Yes
Applicable Trial?:	Section 801 Clinical Trial? Yes Delayed Posting? No
IND/IDE Protocol?:	No
Review Board:	Approval Status: Approved Approval Number: H-C-2007-0047 Board Name: VEK for Region Hovedstaden Board Affiliation: VEK for Region Hovedstaden Phone: +45 4820 5729 Email: vek@regionh.dk
Data Monitoring?:	No
Plan to Share Data?:	
Oversight Authorities:	Argentina: Administracion Nacional de Medicamentos, Alimentos y Tecnologia Medica Australia: Department of Health and Ageing Therapeutic Goods Administration Belgium: Ministerie Van Sociale Zaken Brazil: National Health Surveillance Agency Denmark: Danish Medicines Agency Germany: Bundesinstitut für Arzneimittel und Medizin India: Drug Controller General Philippines: Bureau of Food and Drugs United Kingdom: Information Processing Unit - Area 6

Study Description

Brief Summary:	This study is to assess the effects with two different inhaled respiratory medications with regards to improvement of lung function, symptoms and morning activities.
Detailed Description:	

Conditions

Conditions:	Chronic Obstructive Pulmonary Disease (COPD)
Keywords:	COPD Symbicort Seretide

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 4
Intervention Model:	Crossover Assignment
Number of Arms:	2
Masking:	Double Blind (Subject, Caregiver, Investigator)
Allocation:	Randomized
Endpoint Classification:	Efficacy Study
Enrollment:	442 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Symbicort Turbuhaler First, then Seretide Diskus Symbicort Turbuhaler (budesonide/formoterol) 320/9 µg First, then Seretide Diskus (salmeterol/fluticasone) 50/500 µg	Drug: Symbicort Turbuhaler (budesonide/formoterol) 320/9 µg Drug: Seretide Diskus (salmeterol/fluticasone) 50/500 µg
Experimental: Seretide Diskus First, then Symbicort Turbuhaler Seretide Diskus (salmeterol/fluticasone) 50/500 µg First, then Symbicort Turbuhaler (budesonide/formoterol) 320/9 µg	Drug: Symbicort Turbuhaler (budesonide/formoterol) 320/9 µg Drug: Seretide Diskus (salmeterol/fluticasone) 50/500 µg

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age:	40 Years
Maximum Age:	
Gender:	Both
Accepts Healthy Volunteers?:	No
Criteria:	Inclusion Criteria:

- Outpatient, female or male aged ≥40 years, diagnosis of COPD with symptoms for at least 2 years
- FEV1 ≤50% of predicted normal value, pre-bronchodilator, FEV1/VC <70%

- Pre-bronchodilator

Exclusion Criteria:

- Current respiratory tract disorder other than COPD
- History of asthma or rhinitis
- Significant or unstable cardiovascular disorder

Contacts/Locations

Study Officials: Tomas Andersson, MD
Study Director
AstraZeneca

Martyn R Partridge, MD FRCP
Study Principal Investigator
Faculty of Medicine, Imperial College, NHLI at Charing Cross Hospital, LONDON, UK

Locations: Argentina
Research Site
Monte Grande, Buenos Aires, Argentina

Research Site
Quilmes, Buenos Aires, Argentina

Research Site
San Miguel de Tucuman, Tucuman, Argentina

Research Site
Ciudad Autonoma de Bs. As., Argentina

Research Site
Ciudad de Buenos Aires, Argentina

Australia, New South Wales
Research Site
Concord, New South Wales, Australia

Australia, South Australia
Research Site
Adelaide, South Australia, Australia

Research Site
Daw Park, South Australia, Australia

Research Site
Woodville South, South Australia, Australia

Australia, Victoria
Research Site
Melbourne, Victoria, Australia

Research Site
Parkville, Victoria, Australia

Australia, Western Australia
Research Site
Nedlands, Western Australia, Australia

Belgium
Research Site
Jambes, Belgium, Belgium

Research Site
Malmedy, Belgium, Belgium

Research Site
Montigny-le-tilleul, Belgium, Belgium

Brazil
Research Site
Porto Alegre, Brasil, Brazil

Research Site
Juiz de Fora, MG, Brazil

Research Site
Recife, PE, Brazil

Research Site
Rio de Janeiro, RJ, Brazil

Research Site
Porto Alegre, RS, Brazil

Research Site
Florianopolis, Santa Catarina, Brazil

Research Site
Santo Andre, SP, Brazil

Research Site
Sao Paulo, SP, Brazil

Research Site
Rio de Janeiro, Brazil

Denmark
Research Site
Aalborg, Denmark

Research Site
Alborg, Denmark

Research Site
Hellerup, Denmark

Research Site
Hvidovre, Denmark

Research Site
Kobenhavn Nv, Denmark

Research Site
Odense C, Denmark

Research Site
Rodovre, Denmark

Research Site
Silkeborg, Denmark

Germany
Research Site
Berlin, Germany

Research Site
Erfurt, Germany

Research Site
Leipzig, Germany

Research Site
Marburg, Germany

United Kingdom
Research Site

Dartford, Kent, United Kingdom

Research Site
Hamilton, Lanarkshire, United Kingdom

Research Site
Motherwell, Lanarkshire, United Kingdom

Research Site
Cookstown, N. Ireland, United Kingdom

Research Site
Limavady, Northern Ireland, United Kingdom

Research Site
Newtownabbey, Northern Ireland, United Kingdom

Research Site
Barry, South Glamorgan, United Kingdom

Research Site
Barry, Vale of Glamorgan, United Kingdom

Research Site
Bradford-on-avon, Wiltshire, United Kingdom

Research Site
Airdrie, United Kingdom

Research Site
Birmingham, United Kingdom

Research Site
Blantyre, United Kingdom

Research Site
Bolton, United Kingdom

Research Site
Carrickfergus, United Kingdom

Research Site
Chesterfield, United Kingdom

Research Site
Coventry, United Kingdom

Research Site
Hamilton, United Kingdom

India
Research Site
Hyderabad, Andhra Pradesh, India

Research Site
Bangalore, Karnataka, India

Research Site
Jaipur, Rajasthan, India

Research Site
Coimbatore, India

Research Site
Noida, India

Philippines
Research Site
Manila, Philippines

Research Site
Quezon City, Philippines

References

Citations:

Links:

Study Data/Documents:

Study Results

Participant Flow

Recruitment Details	706 subjects were enrolled; 264 were not randomised: 190 with eligibility not fulfilled, 11 with adverse events, 4 with discontinuation criteria, 40 voluntary discontinuations, 2 lost to follow-ups, 6 non-compliance, 1 for safety reasons, 10 with other reasons not specified. 442 subjects were randomised

Reporting Groups

	Description
Symbicort Turbuhaler First, Then Seretide Diskus	Symbicort Turbuhaler (budesonide/formoterol) 320/9 µg First, then Seretide Diskus (salmeterol/fluticasone) 50/500 µg
Seretide Diskus First, Then Symbicort Turbuhaler	Seretide Diskus (salmeterol/fluticasone) 50/500 µg First, then Symbicort Turbuhaler (budesonide/formoterol) 320/9 µg

Period 1

	Symbicort Turbuhaler First, Then Seretide Diskus	Seretide Diskus First, Then Symbicort Turbuhaler
Started	217 [1]	225
Completed	211	213
Not Completed	6	12
Eligibility criteria not fulfilled	2	6
Adverse Event	2	2
Development of study-specific criteria	1	2
Withdrawal by Subject	1	1
Protocol Violation	0	1

[1] This was a cross-over study

Period 2

	Symbicort Turbuhaler First, Then Seretide Diskus	Seretide Diskus First, Then Symbicort Turbuhaler
Started	211	213
Completed	204	203
Not Completed	7	10
Adverse Event	5	7
Eligibility not fulfilled	0	1
Discontinuation criteria	2	0
Severe non-compliance	0	1
Not specified	0	1

Period 3

	Symbicort Turbuhaler First, Then Seretide Diskus	Seretide Diskus First, Then Symbicort Turbuhaler
Started	204	203
Completed	204	201
Not Completed	0	2
Adverse Event	0	2

Baseline Characteristics

Reporting Groups

	Description
Symbicort Turbuhaler First, Then Seretide Diskus	Symbicort Turbuhaler (budesonide/formoterol) 320/9 µg First, then Seretide Diskus (salmeterol/fluticasone) 50/500 µg
Seretide Diskus First, Then Symbicort Turbuhaler	Seretide Diskus (salmeterol/fluticasone) 50/500 µg First, then Symbicort Turbuhaler (budesonide/formoterol) 320/9 µg

Baseline Measures

	Symbicort Turbuhaler First, Then Seretide Diskus	Seretide Diskus First, Then Symbicort Turbuhaler	Total
Number of Participants	217	225	442
Age, Continuous [units: years] Mean (Full Range)	62.9 (41 to 82)	63.2 (40 to 86)	63.1 (40 to 86)
Gender, Male/Female [units: Participants]			
Female	55	71	126
Male	162	154	316

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Peak Expiratory Flow (PEF) 5 Minutes After Morning Dose
Measure Description	The change from baseline in PEF was calculated using the average over baseline (the last 7 days of run-in and washout period respectively), and all days of treatment, with baseline as covariate.

Time Frame	Baseline (daily records during run-in, and washout) and daily records during the treatment period of 7 days
Safety Issue?	No

Analysis Population Description

Includes all subjects with at least one dose of study medication and who contribute sufficient data for the endpoint to be calculated.

Reporting Groups

	Description
Symbicort Turbuhaler	Symbicort Turbuhaler (budesonide/formoterol) 320/9 µg
Seretide Diskus	Seretide Diskus (salmeterol/fluticasone) 50/500 µg

Measured Values

	Symbicort Turbuhaler	Seretide Diskus
Number of Participants Analyzed	385	390
Peak Expiratory Flow (PEF) 5 Minutes After Morning Dose [units: liters/minute] Mean (Standard Deviation)	15.1 (28.5)	13.4 (28.2)

2. Secondary Outcome Measure:

Measure Title	PEF Before Morning Dose
Measure Description	The change from baseline was calculated using the average over baseline (the last 7 days of run-in and washout period respectively), and over all days of treatment, with baseline as covariate.
Time Frame	Baseline (daily records during run-in, and washout) and daily records during the treatment period of 7 days
Safety Issue?	No

Analysis Population Description

Includes all subjects with at least one dose of study medication and who contribute sufficient data for the endpoint to be calculated.

Reporting Groups

	Description
Symbicort Turbuhaler	Symbicort Turbuhaler (budesonide/formoterol) 320/9 µg
Seretide Diskus	Seretide Diskus (salmeterol/fluticasone) 50/500 µg

Measured Values

	Symbicort Turbuhaler	Seretide Diskus
Number of Participants Analyzed	416	425
PEF Before Morning Dose [units: Liters/minutes] Mean (Standard Deviation)	4.8 (28.2)	7.9 (24)

3. Secondary Outcome Measure:

Measure Title	PEF 15 Minutes After Morning Dose
Measure Description	The change from baseline was calculated using the average over baseline (the last 7 days of run-in and washout period respectively), and over all days of treatment, with baseline as covariate.
Time Frame	Baseline (daily records during run-in, and washout) and daily records during the treatment period of 7 days
Safety Issue?	No

Analysis Population Description

Includes all subjects with at least one dose of study medication and who contribute sufficient data for the endpoint to be calculated.

Reporting Groups

	Description
Symbicort Turbuhaler	Symbicort Turbuhaler (budesonide/formoterol) 320/9 µg
Seretide Diskus	Seretide Diskus (salmeterol/fluticasone) 50/500 µg

Measured Values

	Symbicort Turbuhaler	Seretide Diskus
Number of Participants Analyzed	377	389
PEF 15 Minutes After Morning Dose [units: Liters/minute] Mean (Standard Deviation)	19.9 (30.3)	16.7 (28.5)

4. Secondary Outcome Measure:

Measure Title	PEF Before Evening Dose

Measure Description	The change from baseline was calculated using the average over baseline (the last 7 days of run-in and washout period respectively), and over all days of treatment, with baseline as covariate.
Time Frame	Baseline (daily records during run-in, and washout) and daily records during the treatment period of 7 days
Safety Issue?	No

Analysis Population Description

Includes all subjects with at least one dose of study medication and who contribute sufficient data for the endpoint to be calculated.

Reporting Groups

	Description
Symbicort Turbuhaler	Symbicort Turbuhaler (budesonide/formoterol) 320/9 µg
Seretide Diskus	Seretide Diskus (salmeterol/fluticasone) 50/500 µg

Measured Values

	Symbicort Turbuhaler	Seretide Diskus
Number of Participants Analyzed	418	426
PEF Before Evening Dose [units: Liters/minute] Mean (Standard Deviation)	4 (24.3)	1.8 (50)

5. Secondary Outcome Measure:

Measure Title	Forced Expiratory Volume in 1 Second (FEV1) Before Morning Dose
Measure Description	The change from baseline was calculated using the average over baseline (the last 7 days of run-in and washout period respectively), and over all days of treatment, with baseline as covariate.
Time Frame	Baseline (daily records during run-in, and washout) and daily records during the treatment period of 7 days
Safety Issue?	No

Analysis Population Description

Includes all subjects with at least one dose of study medication and contribute sufficient data for the endpoint to be calculated.

Reporting Groups

	Description
Symbicort Turbuhaler	Symbicort Turbuhaler (budesonide/formoterol) 320/9 µg
Seretide Diskus	Seretide Diskus (salmeterol/fluticasone) 50/500 µg

Measured Values

	Symbicort Turbuhaler	Seretide Diskus
Number of Participants Analyzed	280	269
Forced Expiratory Volume in 1 Second (FEV1) Before Morning Dose [units: Liters] Mean (Standard Deviation)	0.0310 (0.2460)	0.0590 (0.2310)

6. Secondary Outcome Measure:

Measure Title	FEV1 15 Minutes After Morning Dose
Measure Description	The change from baseline was calculated using the average over baseline (the last 7 days of run-in and washout period respectively), and over all days of treatment, with baseline as covariate.
Time Frame	Baseline (daily records during run-in, and washout) and daily records during the treatment period of 7 days
Safety Issue?	No

Analysis Population Description

Includes all subjects with at least one dose of study medication and contribute sufficient data for the endpoint to be calculated.

Reporting Groups

	Description
Symbicort Turbuhaler	Symbicort Turbuhaler (budesonide/formoterol) 320/9 µg
Seretide Diskus	Seretide Diskus (salmeterol/fluticasone) 50/500 µg

Measured Values

	Symbicort Turbuhaler	Seretide Diskus
Number of Participants Analyzed	249	249
FEV1 15 Minutes After Morning Dose [units: Liters] Mean (Standard Deviation)	0.1220 (0.2530)	0.1030 (0.3720)

7. Secondary Outcome Measure:

Measure Title	FEV1 Before Evening Dose
Measure Description	The change from baseline was calculated using the average over baseline (the last 7 days of run-in and washout period respectively), and over all days of treatment, with baseline as covariate.
Time Frame	Baseline (daily records during run-in, and washout) and daily records during the treatment period of 7 days
Safety Issue?	No

Analysis Population Description

Includes all subjects with at least one dose of study medication and who contribute sufficient data for the endpoint to be calculated.

Reporting Groups

	Description
Symbicort Turbuhaler	Symbicort Turbuhaler (budesonide/formoterol) 320/9 µg
Seretide Diskus	Seretide Diskus (salmeterol/fluticasone) 50/500 µg

Measured Values

	Symbicort Turbuhaler	Seretide Diskus
Number of Participants Analyzed	248	243
FEV1 Before Evening Dose [units: Liters] Mean (Standard Deviation)	0.1470 (0.2470)	0.1060 (0.2010)

8. Secondary Outcome Measure:

Measure Title	Change in PEF From Before Dose to 5 Minutes After Dose in the Morning
Measure Description	The change from pre-dose was calculated using the average over baseline (the last 7 days of run-in and washout period respectively), and over all days of treatment, with pre-dose run-in/washout as covariate.
Time Frame	Baseline (daily records during run-in, and washout) and daily records during the treatment period of 7 days
Safety Issue?	No

Analysis Population Description

Includes all subjects with at least one dose of study medication and who contribute sufficient data for the endpoint to be calculated.

Reporting Groups

	Description
Symbicort Turbuhaler	Symbicort Turbuhaler (budesonide/formoterol) 320/9 µg
Seretide Diskus	Seretide Diskus (salmeterol/fluticasone) 50/500 µg

Measured Values

	Symbicort Turbuhaler	Seretide Diskus
Number of Participants Analyzed	279	279
Change in PEF From Before Dose to 5 Minutes After Dose in the Morning [units: Liters/minute] Mean (Standard Deviation)	0.0160 (0.2)	0.0030 (0.299)

9. Secondary Outcome Measure:

Measure Title	Change in PEF From Before Dose to 15 Minutes After Dose in the Morning
Measure Description	The change from pre-dose was calculated using the average over baseline (the last 7 days of run-in and washout period respectively), and over all days of treatment, with mean pre-dose run-in/washout as covariate.
Time Frame	Baseline (daily records during run-in, and washout) and daily records during the treatment period of 7 days
Safety Issue?	No

Analysis Population Description

Includes all subjects with at least one dose of study medication and who contribute sufficient data for the endpoint to be calculated.

Reporting Groups

	Description
Symbicort Turbuhaler	Symbicort Turbuhaler (budesonide/formoterol) 320/9 µg
Seretide Diskus	Seretide Diskus (salmeterol/fluticasone) 50/500 µg

Measured Values

	Symbicort Turbuhaler	Seretide Diskus
Number of Participants Analyzed	368	376
Change in PEF From Before Dose to 15 Minutes After Dose in the Morning [units: Liters/minute]	11.6 (16.2)	6.1 (16.5)

	Symbicort Turbuhaler	Seretide Diskus
Mean (Standard Deviation)		

10. Secondary Outcome Measure:

Measure Title	Change in FEV1from Before Dose to 5 Minutes After Dose in the Morning
Measure Description	The change from pre-dose was calculated using the average over baseline (the last 7 days of run-in and washout period respectively), and over all days of treatment, with mean pre-dose run-in/washout as covariate.
Time Frame	Baseline (daily records during run-in, and washout) and daily records during the treatment period of 7 days
Safety Issue?	No

Analysis Population Description

Includes all subjects with at least one dose of study medication and who contribute sufficient data for the endpoint to be calculated.

Reporting Groups

	Description
Symbicort Turbuhaler	Symbicort Turbuhaler (budesonide/formoterol) 320/9 µg
Seretide Diskus	Seretide Diskus (salmeterol/fluticasone) 50/500 µg

Measured Values

	Symbicort Turbuhaler	Seretide Diskus
Number of Participants Analyzed	368	376
Change in FEV1from Before Dose to 5 Minutes After Dose in the Morning [units: Liters] Mean (Standard Deviation)	15.8 (20.8)	9.6 (19.9)

11. Secondary Outcome Measure:

Measure Title	Change in FEV1 From Before Dose to 15 Minutes After Dose in the Morning
Measure Description	The change from pre-dose was calculated using the average over baseline (the last 7 days of run-in and washout period respectively), and over all days of treatment, with mean pre-dose run-in/washout as covariate.
Time Frame	Baseline (daily records during run-in, and washout) and daily records during the treatment period of 7 days

Safety Issue?	No

Analysis Population Description

Includes all subjects with at least one dose of study medication and who contribute sufficient data for the endpoint to be calculated.

Reporting Groups

	Description
Symbicort Turbuhaler	Symbicort Turbuhaler (budesonide/formoterol) 320/9 µg
Seretide Diskus	Seretide Diskus (salmeterol/fluticasone) 50/500 µg

Measured Values

	Symbicort Turbuhaler	Seretide Diskus
Number of Participants Analyzed	233	238
Change in FEV1 From Before Dose to 15 Minutes After Dose in the Morning [units: Liters] Mean (Standard Deviation)	0.0930 (0.1870)	0.0280 (0.1630)

12. Secondary Outcome Measure:

Measure Title	Change in FEV1 From Before Dose to 5 Minutes After Dose at the Clinic
Measure Description	The change from pre-dose was calculated using the pre-dose baseline value (run-in and washout period respectively), and pre-dose value at day 1, with pre-dose run-in/washout as covariate.
Time Frame	Baseline (run-in, and washout) and day 1 of treatment period
Safety Issue?	No

Analysis Population Description

Includes all subjects with at least one dose of study medication and who contribute sufficient data for the endpoint to be calculated.

Reporting Groups

	Description
Symbicort Turbuhaler	Symbicort Turbuhaler (budesonide/formoterol) 320/9 µg
Seretide Diskus	Seretide Diskus (salmeterol/fluticasone) 50/500 µg

Measured Values

	Symbicort Turbuhaler	Seretide Diskus
Number of Participants Analyzed	233	238
Change in FEV1 From Before Dose to 5 Minutes After Dose at the Clinic [units: Liters] Mean (Standard Deviation)	0.1120 (0.1950)	0.0440 (0.1640)

13. Secondary Outcome Measure:

Measure Title	Change in Forced Vital Capacity (FVC) From Before Dose to5 Minutes After Dose at the Clinic
Measure Description	The change from pre-dose was calculated using the pre-dose baseline value (run-in and washout period respectively), and pre-dose value at day 1, with pre-dose run-in/washout as covariate.
Time Frame	Baseline (run-in, and washout) and day 1 of treatment period
Safety Issue?	No

Analysis Population Description

Includes all subjects with at least one dose of study medication and who contribute sufficient data for the endpoint to be calculated.

Reporting Groups

	Description
Symbicort Turbuhaler	Symbicort Turbuhaler (budesonide/formoterol) 320/9 µg
Seretide Diskus	Seretide Diskus (salmeterol/fluticasone) 50/500 µg

Measured Values

	Symbicort Turbuhaler	Seretide Diskus
Number of Participants Analyzed	415	426
Change in Forced Vital Capacity (FVC) From Before Dose to5 Minutes After Dose at the Clinic [units: Liters] Mean (Standard Deviation)	0.0950 (0.1370)	0.0490 (0.1060)

14. Secondary Outcome Measure:

Measure Title	Capacity of Daily Living in the Morning (CDLM) (Change From Pre to End of Treatment)
Measure Description	The change from baseline was calculated using the average over baseline (the last 7 days of run-in and washout period respectively), and over all days of treatment, with baseline as covariate. Score scale 0 - 5 with 0=worst and 5 = best.
Time Frame	Baseline (daily records during run-in, and washout) and daily records during the treatment period of 7 days
Safety Issue?	Yes

Analysis Population Description

Includes all subjects with at least one dose of study medication and who contribute sufficient data for the endpoint to be calculated.

Reporting Groups

	Description
Symbicort Turbuhaler	Symbicort Turbuhaler (budesonide/formoterol) 320/9 µg
Seretide Diskus First	Seretide Diskus (salmeterol/fluticasone) 50/500 µg

Measured Values

	Symbicort Turbuhaler	Seretide Diskus First
Number of Participants Analyzed	415	426
Capacity of Daily Living in the Morning (CDLM) (Change From Pre to End of Treatment) [units: units on a scale] Mean (Standard Deviation)	0.1920 (0.2530)	0.1240 (0.2310)

15. Secondary Outcome Measure:

Measure Title	Difficulty in Getting Out From Bed (MASQ) (Change From Pre to End of Treatment)
Measure Description	The change from baseline was calculated using the average over baseline (the last 7 days of run-in and washout period respectively), and over all days of treatment, with baseline as covariate. Score scale 0 - 5 with 0=worst and 5 = best.
Time Frame	Baseline (daily records during run-in, and washout) and daily records during the treatment period of 7 days
Safety Issue?	No

Analysis Population Description

Includes all subjects with at least one dose of study medication and who contribute sufficient data for the endpoint to be calculated.

Reporting Groups

	Description
Symbicort Turbuhaler	Symbicort Turbuhaler (budesonide/formoterol) 320/9 µg
Seretide Diskus	Seretide Diskus (salmeterol/fluticasone) 50/500 µg

Measured Values

	Symbicort Turbuhaler	Seretide Diskus
Number of Participants Analyzed	319	311
Difficulty in Getting Out From Bed (MASQ) (Change From Pre to End of Treatment) [units: Units on a scale] Mean (Standard Deviation)	0.21 (0.64)	0.14 (0.75)

16. Secondary Outcome Measure:

Measure Title	The Clinical Chronic Obstructive Pulmonary Disease (COPD) Questionnaire (Change From Pre to End of Treatment)
Measure Description	The change from baseline was calculated using the average over baseline (the last 7 days of run-in and washout period respectively), and over all days of treatment, with baseline as covariate. Score scale 0 - 6 with 0=worst and 6 = best.
Time Frame	Baseline (daily records during run-in, and washout) and daily records during the treatment period of 7 days
Safety Issue?	No

Analysis Population Description

Includes all subjects with at least one dose of study medication and who contribute sufficient data for the endpoint to be calculated.

Reporting Groups

	Description
Symbicort Turbuhaler	Symbicort Turbuhaler (budesonide/formoterol) 320/9 µg
Seretide Diskus	Seretide Diskus (salmeterol/fluticasone) 50/500 µg

Measured Values

	Symbicort Turbuhaler	Seretide Diskus
Number of Participants Analyzed	394	396
The Clinical Chronic Obstructive Pulmonary Disease (COPD) Questionnaire (Change From Pre to End of Treatment)	0.24 (0.75)	0.19 (0.73)

	Symbicort Turbuhaler	Seretide Diskus
[units: Units on a scale] Mean (Standard Deviation)		

Reported Adverse Events

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

Reporting Groups

	Description
Symbicort Turbuhaler	Symbicort Turbuhaler (budesonide/formoterol) 320/9 µg
Seretide Diskus	Seretide Diskus (salmeterol/fluticasone) 50/500 µg

Serious Adverse Events

	Symbicort Turbuhaler	Seretide Diskus
	Affected/At Risk (%)	Affected/At Risk (%)
Total	3/420 (0.71%)	1/429 (0.23%)
General disorders		
Gait disturbance [A] †	1/420 (0.24%)	0/429 (0%)
Respiratory, thoracic and mediastinal disorders		
Chronic obstructive oulmonary disease [A] †	2/420 (0.48%)	1/429 (0.23%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA 11.0

Other Adverse Events

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

	Symbicort Turbuhaler	Seretide Diskus
	Affected/At Risk (%)	Affected/At Risk (%)
Total	0/420 (0%)	0/429 (0%)

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.

Prior to any publication or disclosure, the PI provides AstraZeneca with preliminary data and drafts and with the proposed final manuscript. AstraZeneca shall have a period of 30 days from receipt of the proposed final manuscript to review it and may within such time frame require that submission for publication or disclosure be delayed.

Results Point of Contact:

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