ClinicalTrials.gov Protocol and Results Registration System (PRS) Receipt
Release Date: 10/09/2012

ClinicalTrials.gov ID: NCT00667992

Study Identification

Unique Protocol ID:	D5252C00008
Brief Title:	Study Comparing Budesonide Hydrofluoroalkane (HFA) vs Chlorofluorocarbon (CFC) Pressurized Metered Dose Inhalers (pMDI) in Patients With Mild to Moderate Asthma
Official Title:	A Phase 3, Randomised, Open-label, Crossover Study to Compare HFA vs CFC pMDI Formulations of Budesonide on Methacholine Hyper-reactivity in Patients With Stable, Persistent, Mild to Moderate Asthma
Secondary IDs:	

Study Status

Record Verification:	October 2012
Overall Status:	Completed
Study Start:	April 2008
Primary Completion:	May 2009 [Actual]
Study Completion:	May 2009 [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: 08/S1402/14 (28 Feb 2008) Board Name: NHS Fife, Forth Valley & Tayside Research Ethics Service Board Affiliation: NHS Phone: +44 1382 740099 Email: lorraine.reilly@nhs.net
Data Monitoring?:	No
Plan to Share Data?:	
Oversight Authorities:	United Kingdom: Medicines and Healthcare Products Regulatory Agency

Study Description

Brief Summary:	This study is being carried out to see if budesonide with HFA is effective, safe and well tolerated compared with budesonide CFC. Budesonide HFA has been already given in other research studies, in both healthy volunteers and subjects with asthma.
Detailed Description:	

Conditions

Conditions:	Asthma
Keywords:	Asthma hyperreactivity

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 3
Intervention Model:	Crossover Assignment
Number of Arms:	4
Masking:	Open Label
Allocation:	Randomized
Endpoint Classification:	Bio-equivalence Study

Enrollment: 99 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Active Comparator: Budesonide Hydrofluoroalkane (HFA) 100 Budesonide Hydrofluoroalkane (HFA) 100 mcg twice daily for 2 weeks	Drug: Budesonide HFA standard daily inhaled dose
Active Comparator: Budesonide HFA 400 Budesonide HFA 400 mcg twice daily for 2 weeks	Drug: Budesonide HFA standard daily inhaled dose
Active Comparator: Budesonide Chlorofluorocarbon (CFC) 100 Budesonide Chlorofluorocarbon(CFC) 100 mcg twice daily for 2 weeks	Drug: Budesonide CFC standard daily inhaled dose
Active Comparator: Budesonide CFC 400 Budesonide CFC 400 mcg twice daily for 2 weeks	Drug: Budesonide CFC standard daily inhaled dose

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 18 Years

Maximum Age: 65 Years

Gender: Both

Accepts Healthy Volunteers?: No

Criteria: Inclusion Criteria:

- Patients suffering from stable, persistent, mild to moderate asthma as defined by Global Initiative for Asthma (GINA) Guidelines and for whom FEV1 > 60 %
- ICS taking ≤ 1000 µg BDP per day, or equivalent
- Methacholine PC20 < 4 mg/mL

Exclusion Criteria:

- Known or suspected hypersensitivity to budesonide or any other constituents of the budesonide HFA pMDI or budesonide CFC pMDI.
- Currently a smoker or who has ceased smoking within 6 months of Visit 1.
- Exacerbations of asthma requiring oral steroids, hospitalisation or change in asthma therapy in the previous three months.
- Diagnosis of Chronic Obstructive Pulmonary Disease (COPD) or bronchiectasis

Contacts/Locations

Study Officials: Brian Lipworth, PhD, MD
Study Principal Investigator
Asthma and Allergy Research Group Division of Medicine and Therapeutics Ninewells Hospital and Medical School University of Dundee

Locations: United Kingdom
Research Site
Dundee, Scotland, United Kingdom

Research Site
Perth, Scotland, United Kingdom

United States, Pennsylvania
Research Site
King of Prussia, Pennsylvania, United States

References

Citations:

Links:

Study Data/Documents:

Study Results

Participant Flow

Recruitment Details	144 were enrolled, 45 were excluded: 11 for eligibility not fulfilled, 8 with condition under investigation worsened, 8 for voluntary withdrawal, 17 with reasons not specified, and 1 lost to follow-up and 99 were randomised.

Reporting Groups

	Description
Budesonide Hydrofluoroalkane (HFA) First, Then Budesonide CFC	Budesonide Hydrofluoroalkane (HFA), 100 mcg twice daily followed by Budesonide HFA 400 mcg twice daily First, Wash out, then Budesonide Chlorofluorocarbon (CFC) 100 mcg twice daily followed by Budesonide CFC 400 mcg twice daily.

	Description
Budesonide Chlorofluorocarbon (CFC) First, Then Budesonide HFA	Budesonide CFC, 100 mcg twice daily followed by Budesonide CFC 400 mcg twice daily First, Wash out, then Budesonide HFA 100 mcg twice daily followed by 400 mcg twice daily.

First Intervention 100 mcg Twice Daily

	Budesonide Hydrofluoroalkane (HFA) First, Then Budesonide CFC	Budesonide Chlorofluorocarbon (CFC) First, Then Budesonide HFA
Started	49	50
Completed	44	45
Not Completed	5	5
Condition Under Investigation Worsened	2	3
Withdrawal by Subject	2	0
Adverse Event	0	1
Pregnancy	1	0
Adverse Event	0	1

Second Intervention 400 mcg Twice Daily

	Budesonide Hydrofluoroalkane (HFA) First, Then Budesonide CFC	Budesonide Chlorofluorocarbon (CFC) First, Then Budesonide HFA
Started	44	45
Completed	41	41
Not Completed	3	4
Withdrawal by Subject	1	0
Condition Under Investigation Worsened	2	3
Medication not allowed taken	0	1

Wash-out

	Budesonide Hydrofluoroalkane (HFA) First, Then Budesonide CFC	Budesonide Chlorofluorocarbon (CFC) First, Then Budesonide HFA
Started	41	41
Completed	34	36
Not Completed	7	5

	Budesonide Hydrofluoroalkane (HFA) First, Then Budesonide CFC	Budesonide Chlorofluorocarbon (CFC) First, Then Budesonide HFA
Not within one doubling dilution	4	3
Failure to wash-out	2	2
Withdrawal by Subject	1	0

Third Intervention 100 mcg Twice Daily

	Budesonide Hydrofluoroalkane (HFA) First, Then Budesonide CFC	Budesonide Chlorofluorocarbon (CFC) First, Then Budesonide HFA
Started	34	36
Completed	33	35
Not Completed	1	1
Withdrawal by Subject	1	0
Adverse Event	0	1

Forth Intervention 400 mcg Twice Daily

	Budesonide Hydrofluoroalkane (HFA) First, Then Budesonide CFC	Budesonide Chlorofluorocarbon (CFC) First, Then Budesonide HFA
Started	33	35
Completed	33	35
Not Completed	0	0

Baseline Characteristics

Reporting Groups

	Description
Budesonide Hydrofluoroalkane (HFA) First, Then Budesonide CFC	Budesonide Hydrofluoroalkane (HFA), 100 mcg twice daily followed by Budesonide HFA 400 mcg twice daily, First then Budesonide Chlorofluorocarbon (CFC) 100 mcg twice daily followed by Budesonide CFC 400 mcg twice daily.
Budesonide Chlorofluorocarbon (CFC) First, Then Budesonide HFA	Budesonide CFC, 100 mcg twice daily followed by Budesonide CFC 400 mcg twice daily First, then Budesonide HFA 100 mcg twice daily followed by 400 mcg twice daily.

Baseline Measures

	Budesonide Hydrofluoroalkane (HFA) First, Then Budesonide CFC	Budesonide Chlorofluorocarbon (CFC) First, Then Budesonide HFA	Total
Number of Participants	44	45	89
Age, Continuous [units: years] Mean (Full Range)	40.0 (19.0 to 65.0)	39.5 (18.0 to 64.0)	39.75 (18.0 to 65.0)
Gender, Male/Female [units: Participants]			
Female	24	26	50
Male	20	19	39

Outcome Measures

1. Primary Outcome Measure:

Measure Title	PC 20 Methacholine (Provocative Concentration of Methacholine Causing 20 % Fall in FEV1(Forced Expiratory Volume)
Measure Description	Provocative concentration of methacholine is that causing a 20% fall in FEV1. The methacholine challenge test entailed the patient inhaling from an aerosol containing doubling concentrations of methacholine over a period of 2 minutes until FEV1 had been reduced by 20%. The ratio of Methacholine concentration measured at 2 weeks to that at Baseline.
Time Frame	Baseline and week 2
Safety Issue?	No

Analysis Population Description

Full analysis set (FAS). The FAS was defined as all randomised patients who contributed data from at least one period (ie data from both low and high dose of one inhaler).

Reporting Groups

	Description
Budesonide Hydrofluoroalkane (HFA) 100	Budesonide Hydrofluoroalkane (HFA) 100 mcg twice daily for 2 weeks
Budesonide HFA 400	Budesonide HFA 400 mcg twice daily for 2 weeks
Budesonide Chlorofluorocarbon(CFC) 100	Budesonide Chlorofluorocarbon (CFC) 100 mcg twice daily for 2 weeks

	Description
Budesonide CFC 400	Budesonide CFC 400 mcg twice daily for 2 weeks

Measured Values

	Budesonide Hydrofluoroalkane (HFA) 100	Budesonide HFA 400	Budesonide Chlorofluorocarbon(CFC 100	Budesonide CFC 400
Number of Participants Analyzed	80	79	79	78
PC 20 Methacholine (Provocative Concentration of Methacholine Causing 20 % Fall in FEV1(Forced Expiratory Volume) [units: Ratio] Geometric Mean (95% Confidence Interval)	1.546 (1.343 to 1.780)	2.163 (1.877 to 2.494)	1.673 (1.449 to 1.928)	2.079 (1.801 to 2.401)

2. Secondary Outcome Measure:

Measure Title	Peak Exploratory Flow (PEF)
Measure Description	Change in PEF at Week 2 from baseline, mean over all days in run-in and all dasy in treatment period, with baseline as covariate.
Time Frame	Baseline to week 2 recorded daily
Safety Issue?	No

Analysis Population Description

Full analysis set (FAS). The FAS was defined as all randomised patients who contributed data from at least one period (ie data from both low and high dose of one inhaler).

Reporting Groups

	Description
Budesonide Hydrofluoroalkane (HFA) 100	Budesonide Hydrofluoroalkane (HFA) 100 mcg twice daily for 2 weeks
Budesonide HFA 400	Budesonide HFA 400 mcg twice daily for 2 weeks
Budesonide Chlorofluorocarbon(CFC) 100	Budesonide Chlorofluorocarbon(CFC) 100 mcg twice daily for 2 weeks
Budesonide CFC 400	Budesonide CFC 400 mcg twice daily for 2 weeks

Measured Values

	Budesonide Hydrofluoroalkane (HFA) 100	Budesonide HFA 400	Budesonide Chlorofluorocarbon(CFC 100	Budesonide CFC 400
Number of Participants Analyzed	80	79	79	78
Peak Exploratory Flow (PEF) [units: Liters/minutes] Least Squares Mean (95% Confidence Interval)	9.7 (3.9 to 15.6)	12.7 (6.8 to 18.6)	12.0 (6.1 to 17.9)	9.1 (3.2 to 15.1)

3. Secondary Outcome Measure:

Measure Title	FEV1 (Forced Expiratory Volume in 1 Second)
Measure Description	FEV1 change from baseline
Time Frame	Baseline to week 2
Safety Issue?	No

Analysis Population Description

Full analysis set (FAS). The FAS was defined as all randomised patients who contributed data from at least one period (ie data from both low and high dose of one inhaler).

Reporting Groups

	Description
Budesonide Hydrofluoroalkane(HFA) 100	Budesonide Hydrofluoroalkane(HFA) 100 mcg twice daily for 2 weeks
Budesonide HFA 400	Budesonide HFA 400 mcg twice daily for 2 weeks
Budesonide Chlorofluorocarbon (CFC) 100	Budesonide Chlorofluorocarbon(CFC) 100 mcg twice daily for 2 weeks
Budesonide CFC 400	Budesonide CFC 400 mcg twice daily for 2 weeks

Measured Values

	Budesonide Hydrofluoroalkane(HFA) 100	Budesonide HFA 400	Budesonide Chlorofluorocarbon (CFC) 100	Budesonide CFC 400
Number of Participants Analyzed	80	79	79	78
FEV1 (Forced Expiratory Volume in 1 Second) [units: Liters]	0.08 (0.05 to 0.11)	0.10 (0.07 to 0.13)	0.10 (0.07 to 0.13)	0.11 (0.08 to 0.14)

	Budesonide Hydrofluoroalkane(HFA) 100	Budesonide HFA 400	Budesonide Chlorofluorocarbon (CFC) 100	Budesonide CFC 400
Least Squares Mean (95% Confidence Interval)				

4. Secondary Outcome Measure:

Measure Title	FEF 25-75 (Forced Expiratory Flow 25-75)
Measure Description	FEF 25-75- Forced expiratory flow over the middle one half of the FVC. The results are expressed as the change from baseline
Time Frame	Baseline and week 2
Safety Issue?	No

Analysis Population Description

Full analysis set (FAS). The FAS was defined as all randomised patients who contributed data from at least one period (ie data from both low and high dose of one inhaler).

Reporting Groups

	Description
Budesonide Hydrofluoroalkane(HFA) 100	Budesonide Hydrofluoroalkane(HFA) 100 mcg twice daily for 2 weeks
Budesonide HFA 400	Budesonide HFA 400 mcg twice daily for 2 weeks
Budesonide Chlorofluorocarbon (CFC) 100	Budesonide Chlorofluorocarbon(CFC) 100 mcg twice daily for 2 weeks
Budesonide CFC 400	Budesonide CFC 400 mcg twice daily for 2 weeks

Measured Values

	Budesonide Hydrofluoroalkane(HFA) 100	Budesonide HFA 400	Budesonide Chlorofluorocarbon (CFC) 100	Budesonide CFC 400
Number of Participants Analyzed	80	79	79	78
FEF 25-75 (Forced Expiratory Flow 25-75) [units: Liters/seconds] Least Squares Mean (95% Confidence Interval)	0.11 (0.005 to 0.17)	0.14 (0.08 to 0.20)	0.15 (0.09 to 0.21)	0.20 (0.13 to 0.26)

5. Secondary Outcome Measure:

Measure Title	eNO (Exhaled Nitrogen Oxide)
Measure Description	eNO ratio of baseline
Time Frame	baseline and week 2
Safety Issue?	No

Analysis Population Description

Full analysis set (FAS). The FAS was defined as all randomised patients who contributed data from at least one period (ie data from both low and high dose of one inhaler).

Reporting Groups

	Description
Budesonide Hydrofluoroalkane(HFA) 100	Budesonide Hydrofluoroalkane(HFA) 100 mcg twice daily for 2 weeks
Budesonide HFA 400	Budesonide HFA 400 mcg twice daily for 2 weeks
Budesonide Chlorofluorocarbon (CFC) 100	Budesonide Chlorofluorocarbon (CFC) 100 mcg twice daily for 2 weeks
Budesonide CFC 400	Budesonide CFC 400 mcg twice daily for 2 weeks

Measured Values

	Budesonide Hydrofluoroalkane(HFA) 100	Budesonide HFA 400	Budesonide Chlorofluorocarbon (CFC) 100	Budesonide CFC 400
Number of Participants Analyzed	80	79	79	78
eNO (Exhaled Nitrogen Oxide) [units: Ratio] Geometric Mean (95% Confidence Interval)	0.66 (0.62 to 0.70)	0.57 (0.53 to 0.60)	0.66 (0.63 to 0.70)	0.59 (0.55 to 0.62)

6. Secondary Outcome Measure:

Measure Title	Asthma Symptom Score Morning

Measure Description	Asthma Symptom score recorded daily in the morning: Scale: 0-3. 0 = None; no asthma symptoms. 1 = Mild symptoms; aware of asthma symptoms but easily tolerated. 2 = Moderate symptoms; asthma causing enough discomfort to cause problems with normal activities (or with sleep). 3 =Severe symptoms; unable to do normal activities. The average of means for values recorded daily in the morning is presented.
Time Frame	2 weeks
Safety Issue?	No

Analysis Population Description

Full analysis set (FAS). The FAS was defined as all randomised patients who contributed data from at least one period (ie data from both low and high dose of one inhaler).

Reporting Groups

	Description
Budesonide Hydrofluoroalkane(HFA) 100	Budesonide Hydrofluoroalkane(HFA) 100 mcg twice daily for 2 weeks
Budesonide HFA 400	Budesonide HFA 400 mcg twice daily for 2 weeks
Budesonide Chlorofluorocarbon(CFC) 100	Budesonide Chlorofluorocarbon (CFC) 100 mcg twice daily for 2 weeks
Budesonide CFC 400	Budesonide CFC 400 mcg twice daily for 2 weeks

Measured Values

	Budesonide Hydrofluoroalkane(HFA) 100	Budesonide HFA 400	Budesonide Chlorofluorocarbon(CFC) 100	Budesonide CFC 400
Number of Participants Analyzed	80	79	79	78
Asthma Symptom Score Morning [units: Units on a scale] Least Squares Mean (95% Confidence Interval)	0.39 (0.34 to 0.44)	0.29 (0.24 to 0.34)	0.39 (0.34 to 0.44)	0.30 (0.25 to 0.35)

7. Secondary Outcome Measure:

Measure Title	Asthma Symptom Score Evening
Measure Description	Asthma Symptom score recorded daily in the evening: Scale: 0-3. 0 = None; no asthma symptoms. 1 = Mild symptoms; aware of asthma symptoms but easily tolerated. 2 = Moderate symptoms; asthma causing enough discomfort to cause problems with normal activities (or with sleep). 3 =Severe symptoms; unable to do normal activities. The average of means for values recorded daily in the evening is presented.

Time Frame	2 weeks
Safety Issue?	No

Analysis Population Description

Full analysis set (FAS). The FAS was defined as all randomised patients who contributed data from at least one period (ie data from both low and high dose of one inhaler).

Reporting Groups

	Description
Budesonide Hydrofluoroalkane(HFA) 100	Budesonide Hydrofluoroalkane (HFA) 100 mcg twice daily for 2 weeks
Budesonide HFA 400	Budesonide HFA 400 mcg twice daily for 2 weeks
Budesonide Chlorofluorocarbon (CFC) 100	Budesonide Chlorofluorocarbon (CFC) 100 mcg twice daily for 2 weeks
Budesonide CFC 400	Budesonide CFC 400 mcg twice daily for 2 weeks

Measured Values

	Budesonide Hydrofluoroalkane(HFA) 100	Budesonide HFA 400	Budesonide Chlorofluorocarbon (CFC) 100	Budesonide CFC 400
Number of Participants Analyzed	80	79	79	78
Asthma Symptom Score Evening [units: Units on a scale] Least Squares Mean (95% Confidence Interval)	0.48 (0.43 to 0.52)	0.32 (0.27 to 0.38)	0.46 (0.41 to 0.50)	0.36 (0.31 to 0.41)

8. Secondary Outcome Measure:

Measure Title	Asthma Symptom Score Total
Measure Description	Asthma Symptom score recoded daily, Total. Scale: 0 - 3. 0 = None; no asthma symptoms. 1 = Mild symptoms; aware of asthma symptoms but easily tolerated. 2 = Moderate symptoms; asthma causing enough discomfort to cause problems with normal activities (or with sleep). 3 =Severe symptoms; unable to do normal activities. The average of means for values recorded daily is presented.
Time Frame	2 weeks
Safety Issue?	No

Analysis Population Description

Full analysis set (FAS). The FAS was defined as all randomised patients who contributed data from at least one period (ie data from both low and high dose of one inhaler).

Reporting Groups

	Description
Budesonide Hydrofluoroalkane(HFA) 100	Budesonide Hydrofluoroalkane (HFA) 100 mcg twice daily for 2 weeks
Budesonide HFA 400	Budesonide HFA 400 mcg twice daily for 2 weeks
Budesonide Chlorofluorocarbon (CFC) 100	Budesonide Chlorofluorocarbon (CFC) 100 mcg twice daily for 2 weeks
Budesonide CFC 400	Budesonide CFC 400 mcg twice daily for 2 weeks

Measured Values

	Budesonide Hydrofluoroalkane(HFA) 100	Budesonide HFA 400	Budesonide Chlorofluorocarbon (CFC) 100	Budesonide CFC 400
Number of Participants Analyzed	80	79	79	78
Asthma Symptom Score Total [units: Units on a scale] Least Squares Mean (95% Confidence Interval)	0.87 (0.78 to 0.96)	0.61 (0.52 to 0.71)	0.85 (0.76 to 0.94)	0.66 (0.56 to 0.76)

9. Secondary Outcome Measure:

Measure Title	Rescue Medication Morning
Measure Description	The average of means for inhalations of rescue medication in the morning is presented.
Time Frame	2 weeks
Safety Issue?	No

Analysis Population Description

Full analysis set (FAS). The FAS was defined as all randomised patients who contributed data from at least one period (ie data from both low and high dose of one inhaler).

Reporting Groups

	Description
Budesonide Hydrofluoroalkane (HFA) 100	Budesonide Hydrofluoroalkane(HFA) 100 mcg twice daily for 2 weeks
Budesonide HFA 400	Budesonide HFA 400 mcg twice daily for 2 weeks
Budesonide Chlorofluorocarbon (CFC) 100	Budesonide Chlorofluorocarbon (CFC) 100 mcg twice daily for 2 weeks
Budesonide CFC 400	Budesonide CFC 400 mcg twice daily for 2 weeks

Measured Values

	Budesonide Hydrofluoroalkane (HFA) 100	Budesonide HFA 400	Budesonide Chlorofluorocarbon (CFC) 100	Budesonide CFC 400
Number of Participants Analyzed	80	79	79	78
Rescue Medication Morning [units: Number of inhalations] Least Squares Mean (95% Confidence Interval)	0.71 (0.60 to 0.82)	0.45 (0.34 to 0.56)	0.62 (0.51 to 0.73)	0.50 (0.39 to 0.61)

10. Secondary Outcome Measure:

Measure Title	Rescue Medication Evening
Measure Description	The average of means for inhalations of rescue medication in the evening is presented.
Time Frame	2 weeks
Safety Issue?	No

Analysis Population Description

Full analysis set (FAS). The FAS was defined as all randomised patients who contributed data from at least one period (ie data from both low and high dose of one inhaler).

Reporting Groups

	Description
Budesonide Hydrofluoroalkane(HFA) 100	Budesonide Hydrofluoroalkane(HFA) 100 mcg twice daily for 2 weeks
Budesonide HFA 400	Budesonide HFA 400 mcg twice daily for 2 weeks

	Description
Budesonide Chlorofluorocarbon (CFC) 100	Budesonide Chlorofluorocarbon(CFC) 100 mcg twice daily for 2 weeks
Budesonide CFC 400	Budesonide CFC 400 mcg twice daily for 2 weeks

Measured Values

	Budesonide Hydrofluoroalkane(HFA) 100	Budesonide HFA 400	Budesonide Chlorofluorocarbon (CFC) 100	Budesonide CFC 400
Number of Participants Analyzed	80	79	79	78
Rescue Medication Evening [units: Number of inhalations] Least Squares Mean (95% Confidence Interval)	0.90 (0.77 to 1.03)	0.67 (0.52 to 0.80)	0.84 (0.71 to 0.97)	0.64 (0.50 to 0.78)

11. Secondary Outcome Measure:

Measure Title	Rescue Medication Total
Measure Description	The average of means for inhalations of rescue medication in morning and evening combined over a 24 hour period is presented.
Time Frame	2 weeks
Safety Issue?	No

Analysis Population Description

Full analysis set (FAS). The FAS was defined as all randomised patients who contributed data from at least one period (ie data from both low and high dose of one inhaler).

Reporting Groups

	Description
Budesonide Hydrofluoroalkane (HFA) 100	Budesonide Hydrofluoroalkane(HFA) 100 mcg twice daily for 2 weeks
Budesonide HFA 400	Budesonide HFA 400 mcg twice daily for 2 weeks
Budesonide Chlorofluorocarbon(CFC) 100	Budesonide Chlorofluorocarbon (CFC) 100 mcg twice daily for 2 weeks
Budesonide CFC 400	Budesonide CFC 400 mcg twice daily for 2 weeks

Measured Values

	Budesonide Hydrofluoroalkane (HFA) 100	Budesonide HFA 400	Budesonide Chlorofluorocarbon(CFC 100	Budesonide CFC 400
Number of Participants Analyzed	80	79	79	78
Rescue Medication Total [units: Number of inhalations/24 hours] Least Squares Mean (95% Confidence Interval)	1.58 (1.35 to 1.80)	1.10 (0.86 to 1.33)	1.39 (1.16 to 1.62)	1.05 (0.81 to 1.29)

12. Secondary Outcome Measure:

Measure Title	Peak Exploratory Flow (PEF) Morning
Measure Description	Peak Exploratory Flow (PEF) recorded daily in the morning
Time Frame	2 weeks
Safety Issue?	No

Analysis Population Description

Full analysis set (FAS). The FAS was defined as all randomised patients who contributed data from at least one period (ie data from both low and high dose of one inhaler).

Reporting Groups

	Description
Budesonide Hydrofluoroalkane (HFA) 100	Budesonide Hydrofluoroalkane(HFA) 100 mcg twice daily for 2 weeks
Budesonide HFA 400	Budesonide HFA 400 mcg twice daily for 2 weeks
Budesonide Chlorofluorocarbon (CFC) 100	Budesonide Chlorofluorocarbon (CFC) 100 mcg twice daily for 2 weeks
Budesonide CFC 400	Budesonide CFC 400 mcg twice daily for 2 weeks

Measured Values

	Budesonide Hydrofluoroalkane (HFA) 100	Budesonide HFA 400	Budesonide Chlorofluorocarbon (CFC) 100	Budesonide CFC 400
Number of Participants Analyzed	80	79	79	78
Peak Exploratory Flow (PEF) Morning [units: Liters/minutes]	426 (421 to 431)	437 (433 to 442)	428 (424 to 433)	438 (433 to 442)

	Budesonide Hydrofluoroalkane (HFA) 100	Budesonide HFA 400	Budesonide Chlorofluorocarbon (CFC) 100	Budesonide CFC 400
Least Squares Mean (95% Confidence Interval)				

Reported Adverse Events

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

Reporting Groups

	Description
Budesonide Hydrofluoroalkane (HFA) 100	Budesonide Hydrofluoroalkane (HFA) 100 mcg twice daily for 2 weeks
Budesonide HFA 400	Budesonide HFA 400 mcg twice daily for 2 weeks
Budesonide Chlorofluorocarbon (CFC) 100	Budesonide Chlorofluorocarbon (CFC) 100 mcg twice daily for 2 weeks
Budesonide CFC 400	Budesonide CFC 400 mcg twice daily for 2 weeks

Serious Adverse Events

	Budesonide Hydrofluoroalkane (HFA) 100	Budesonide HFA 400	Budesonide Chlorofluorocarbon (CFC) 100	Budesonide CFC 400
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	0/86 (0%)	1/81 (1.23%)	2/85 (2.35%)	0/79 (0%)
Infections and infestations				
Lower Respiratory Tract Infection [A] †	0/86 (0%)	0/81 (0%)	1/85 (1.18%)	0/79 (0%)
Oral Candidiasis [A] †	0/86 (0%)	1/81 (1.23%)	0/85 (0%)	0/79 (0%)
Respiratory Tract Infection Viral [A] †	0/86 (0%)	0/81 (0%)	1/85 (1.18%)	0/79 (0%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRa 10.0

Other Adverse Events

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

	Budesonide Hydrofluoroalkane (HFA) 100	Budesonide HFA 400	Budesonide Chlorofluorocarbon (CFC) 100	Budesonide CFC 400
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	0/86 (0%)	0/81 (0%)	0/85 (0%)	0/79 (0%)

Limitations and Caveats

[Not specified]

More Information

Certain Agreements:

Principal Investigators are NOT employed by the organization sponsoring the study.

There is NOT 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.

Results Point of Contact:

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