Asthma Study Comparing Anti-Inflammatory Effects of 3 Doses of Mometasone Furoate/Formoterol Fumarate and Medium Dose Mometasone Furoate (Study P05122 AM1)(COMPLETED)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

Information provided by (Responsible Party):
Merck Sharp & Dohme Corp.

ClinicalTrials.gov Identifier:
NCT00635882

First received: January 21, 2008
Last updated: September 18, 2015
Last verified: September 2015
History of Changes

Purpose

This is a 2-week double-blind, placebo-controlled, parallel group study comparing the anti-inflammatory effects of low, medium, and high dose mometasone furoate/formoterol fumarate (MF/F) metered dose inhaler (MDI) formulation and medium dose mometasone furoate (MF) dry powder inhaler (DPI) and MDI formulations in adults and adolescents with persistent allergic asthma.

Condition	Intervention	Phase
Asthma Airway Inflammation	Drug: mometasone furoate/formoterol 100/10 mcg Drug: mometasone furoate/formoterol 200/10 mcg Drug: mometasone furoate/formoterol 400/10 mcg Drug: MF DPI 200 mcg Drug: MF MDI 200 mcg Drug: Placebo	Phase 2

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Efficacy Study
Intervention Model: Parallel Assignment
Masking: Double Blind (Subject, Caregiver, Investigator)
Primary Purpose: Treatment

Official Title: A 2-Week Double-Blind, Placebo-Controlled, Parallel Group Study Comparing the Anti-Inflammatory Effects of Low, Medium, and High Dose Mometasone Furoate/Formoterol Fumarate MDI Formulation and Medium Dose Mometasone Furoate DPI and MDI Formulations in Adults and Adolescents With Persistent Allergic Asthma

Resource links provided by NLM:

Genetics Home Reference related topics: allergic asthma

Drug Information available for: Formoterol fumarate Formoterol Mometasone furoate Mometasone furoate monohydrate Arformoterol Tartrate

U.S. FDA Resources

Further study details as provided by Merck Sharp & Dohme Corp.:

Primary Outcome Measures:

- Mean Percent Change From Baseline to Day 14 in Exhaled Nitric Oxide (eNO) Parts Per Billion (Ppb) [Time Frame: Baseline to Day 14] [Designated as safety issue: No]

Secondary Outcome Measures:

- Mean Percent Change From Baseline to Day 7 in eNO Ppb [Time Frame: Baseline to Day 7] [Designated as safety issue: No]
- Mean Percent Change From Baseline to Day 14 in Sputum Eosinophil Count (Percentage) [Time Frame: Baseline to Day 14] [Designated as safety issue: No]
- Mean Change From Baseline to Day 15 of Mannitol Challenge [Time Frame: Baseline to Day 15] [Designated as safety issue: No]

  Mannitol challenge (also referred to as PD15) is the provocative dose of mannitol required to produce a 15% reduction in the forced expiratory volume (in liters) in one second (FEV1).

- Change From Baseline in AM Total Asthma Symptom Score at Days 2-15 [Time Frame: Baseline and Days 2-15] [Designated as safety issue: No]

  Twice daily, participants rated the following asthma symptoms as experienced during the time period since the last evaluation: wheezing, difficulty breathing, and cough on a scale of 0 (none) to 3 (severe, very uncomfortable and interfered with most or all of normal daily activities/sleep). The total asthma symptom score ranged from 0 to 9. The results were recorded in the participant's diary.

- Change From Baseline in PM Total Asthma Symptom Score at Days 1-15 [Time Frame: Baseline and Days 1-15] [Designated as safety issue: No]

  Twice daily, participants rated the following asthma symptoms as experienced during the time period since the last evaluation: wheezing, difficulty breathing, and cough on a scale of 0 (none) to 3 (severe, very uncomfortable and interfered with most or all of normal daily activities/sleep). The total asthma symptom score ranged from 0 to 9. The results were recorded in the participant's diary.

- Change From Baseline in AM Peak Expiratory Flow (PEF) at Days 2-15 [Time Frame: Baseline and Days 2-15] [Designated as safety issue: No]
- Change From Baseline in PM PEF at Days 1-15 [Time Frame: Baseline and Days 1-15] [Designated as safety issue: No]

Other Outcome Measures:

- Baseline Exhaled Nitric Oxide (eNO) Parts Per Billion (Ppb) [Time Frame: Baseline] [Designated as safety issue: No]

Enrollment:	93
Study Start Date:	February 2008
Study Completion Date:	June 2009
Primary Completion Date:	June 2009 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: MF/F MDI 100/10 mcg	Drug: mometasone furoate/formoterol 100/10 mcg mometasone furoate/formoterol 100/10 mcg twice daily (BID) (two inhalations of MF/F 50/5 from a metered-dose inhaler) for 14 days Other Name: MF/F (SCH 418131)
Experimental: MF/F MDI 200/10 mcg	Drug: mometasone furoate/formoterol 200/10 mcg mometasone furoate/formoterol 200/10 mcg twice daily (BID) (two inhalations of MF/F 100/5 from a metered-dose inhaler) for 14 days Other Name: MF/F 200/10 (SCH 418131)
Experimental: MF/F MDI 400/10 mcg	Drug: mometasone furoate/formoterol 400/10 mcg mometasone furoate/formoterol 400/10 mcg twice daily (BID) (two inhalations of MF/F 200/5 mcg from a metered-dose inhaler) for 14 days Other Name: MF/F 400/10 (SCH 418131)

Experimental: MF DPI 200 mcg	Drug: MF DPI 200 mcg MF DPI 200 mcg twice daily (BID) (one inhalation of MF DPI 200 mcg) for 14 days Other Name: mometasone furoate (SCH 32088)
Experimental: MF MDI 200 mcg	Drug: MF MDI 200 mcg MF MDI 200 mcg twice daily (BID) (two inhalations of MF MDI 100 mcg) for 14 days Other Name: mometasone furoate (SCH 32088)
Experimental: Placebo	Drug: Placebo MF/F MDI placebo twice daily (BID) (2 inhalations)

Detailed Description:

This is a 2-week double-blind, placebo-controlled, parallel group study comparing the anti-inflammatory effects of low, medium, and high dose mometasone furoate/formoterol fumarate MDI formulation and medium dose mometasone furoate (MF) DPI and MDI formulations in adults and adolescents with persistent allergic asthma. An open-label run in period is to be followed by a double-blind treatment period.

A total of 90 subjects (15 per treatment) will be enrolled to ensure 12 subjects per treatment at the Day 14 evaluation, accounting for a 20% drop-out rate. A sample size of 12 subjects per treatment is required to detect a treatment difference of 28% in percent change of eNO at Day 14, assuming a pooled standard deviation of 20% with a power of 90%. These estimates are based on examination of eNO levels in asthmatic vs healthy subjects in an article written by S.A. Kharitonov et. al, 2003.

Subjects will be randomized to one of six treatment groups (MF/F MDI 100/10 mcg BID, MF/F MDI 200/10 mcg BID, MF/F MDI 400/10 mcg BID, MF DPI 200 mcg BID, MF MDI 200 mcg BID, or Placebo MDI BID) according to an Schering-Plough Research Institute (SPRI) computer-generated randomization schedule. Randomization will be performed in appropriately sized blocks using random numbers generated by statistical analysis software (SAS).

Eligibility

Ages Eligible for Study: 12 Years and older
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- To document asthma diagnosis, historical reversibility defined as an increase in absolute forced expiratory volume (in liters) in 1 second (FEV1) of >= 12% and >= 200 mL must have been performed within 12 months of Screening. For subjects without historical reversibility, one of the following methods can be used at the Screening Visit or at any time before the Baseline Visit:
  - Demonstration of an increase in absolute FEV1 of at least 12% and a volume increase of at least 200 mL within 15-20 minutes after administration of 4 inhalations of albuterol/salbutamol (total dose 360 to 400 mcg) or of nebulized short-acting beta agonist (SABA) (2.5 mg), if confirmed as standard office practice, OR
  - Demonstration of a peak expiratory flow (PEF) variability of more than 20% expressed as a percentage of the mean highest and lowest morning prebronchodilator PEF over at least 1 week, OR
  - Demonstration of a diurnal variation PEF of more than 20% based on the difference between the prebronchodilator (before taking albuterol/salbutamol) morning value and the postbronchodilator value (after taking albuterol/salbutamol) from the evening before, expressed as a percentage of the mean daily PEF value on any day during the open-label Run-in Period. {The calculation formula: Diurnal PEF Variation = Absolute [(highest of 3 readings, PM Post-bronchodilator (BD) PEF from prior evening) - (highest of 3 readings, AM Pre-BD from morning value)]/[(highest PM Post-BD + highest AM Pre-BD)/2] * 100}
- At Screening and Baseline Visits, a subject must have persistent allergic asthma with an FEV1 >65% predicted.
- A subject must be allergic to at least one common allergen (grasses, trees, weeds, house dust mites, molds, dog and cat) as demonstrated by clinical symptoms when exposed to the allergen(s), and by skin prick testing or a radioallergosorbent (RAST) class >1 (excluding modified RAST procedure [mRAST]) within 2 years of inclusion in the study.
- If, based upon the medical judgment of the investigator, there is no inherent harm in changing the subject's current asthma therapy, the subject and/or parent/guardian) must agree to discontinue prescribed inhaled corticosteroid (ICS), anticholinergics, leukotriene receptor inhibitors, and long-acting beta-2 agonists at the Screening Visit as per required washouts, and be transferred to treatment with SABA for relief for 2 weeks before the Baseline/Randomization Visit.
- Clinical laboratory tests (complete blood count, blood chemistries, and urinalysis) conducted at the Screening Visit must be within normal limits or clinically acceptable to the investigator.
- An electrocardiogram (ECG) performed at the Screening Visit or within 30 days prior to Screening Visit must be clinically acceptable to the investigator and have a QTc interval <440 milliseconds for males and <450 msec for females.
- At Screening or any time prior to Baseline, a subject must have an eNO level of >30 parts per billion (ppb) at a flow rate of 50 mL/second.

- At Screening or any time before Baseline, a subject must have a sputum eosinophil count >3% of total cell count.
- Willingness to give written informed consent and ability to adhere to dose and visit schedules. A subject 12 to 17 years of age must also provide written assent.
- A nonpregnant female subject of childbearing potential (with a negative serum pregnancy test at Screening) must use a medically acceptable, adequate form of birth control. If not currently sexually active she must agree to use a double-barrier method if she becomes sexually active during the study.

Exclusion Criteria:

- Use of systemic glucocorticosteroids within 3 months before Screening.
- Upper or lower respiratory tract infection within 4 weeks before Screening.
- Decrease in absolute FEV1 >20% between Screening and Baseline Visits.
- Requirement for > 8 inhalations per day of SABA MDI, or 2 or more nebulized treatments of 2.5 mg SABA, on any 2 consecutive days between the Screening and Baseline Visits.
- A decrease in AM or PM PEF below the Run-in Period stability limit on any 2 consecutive days before Baseline. At Visit 1, the Run-in Period stability limit for PEF will be established based on the subject's personal best. If the subject does not have a historical personal best, the historical PEF measurement will be the PEF predicted based on the subject's sex, age, and height. PEF value to be multiplied by 0.70 to determine stability limit.
- A clinical asthma exacerbation defined as a clinical deterioration of asthma that results in emergency treatment, hospitalization for asthma, or treatment with additional, excluded asthma medication (including oral or other systemic corticosteroids but allowing SABA), as per investigator, between Screening and Baseline Visits.
- Inability to induce sputum after 1 or 2 trys.

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

No Contacts or Locations Provided

More Information

Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

Nolte H, Pavord I, Backer V, Spector S, Shekar T, Gates D, Nair P, Hargreave F. Dose-dependent anti-inflammatory effect of inhaled mometasone furoate/formoterol in subjects with asthma. Respir Med. 2013 May;107(5):656-64. doi: 10.1016/j.rmed.2013.02.010. Epub 2013 Mar 13.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00635882 History of Changes
Other Study ID Numbers:	P05122
Study First Received:	January 21, 2008
Results First Received:	October 22, 2010
Last Updated:	September 18, 2015
Health Authority:	United States: Food and Drug Administration

Keywords provided by Merck Sharp & Dohme Corp.:
mometasone
formoterol

Additional relevant MeSH terms:

Asthma	Adrenergic Agonists
Inflammation	Adrenergic beta-2 Receptor Agonists
Bronchial Diseases	Adrenergic beta-Agonists
Hypersensitivity	Anti-Allergic Agents
Hypersensitivity, Immediate	Anti-Asthmatic Agents
Immune System Diseases	Autonomic Agents
Lung Diseases	Bronchodilator Agents
Lung Diseases, Obstructive	Molecular Mechanisms of Pharmacological Action
Pathologic Processes	Neurotransmitter Agents

Respiratory Hypersensitivity
Respiratory Tract Diseases
Anti-Inflammatory Agents
Formoterol
Mometasone furoate
Adrenergic Agents
Peripheral Nervous System Agents
Pharmacologic Actions
Physiological Effects of Drugs
Respiratory System Agents
Therapeutic Uses

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Asthma Study Comparing Anti-Inflammatory Effects of 3 Doses of Mometasone Furoate/Formoterol Fumarate and Medium Dose Mometasone Furoate (Study P05122 AM1)(COMPLETED)

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Sponsor:
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ClinicalTrials.gov Identifier:
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First received: January 21, 2008
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History of Changes

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Results First Received: October 22, 2010

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Caregiver, Investigator); Primary Purpose: Treatment
Conditions:	Asthma Airway Inflammation
Interventions:	Drug: mometasone furoate/formoterol 100/10 mcg Drug: mometasone furoate/formoterol 200/10 mcg Drug: mometasone furoate/formoterol 400/10 mcg Drug: MF DPI 200 mcg Drug: MF MDI 200 mcg Drug: Placebo

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations

No text entered.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment

No text entered.

Reporting Groups

	Description
MF/F MDI 100/10 mcg	Mometasone furoate/formoterol fumarate (MF/F) metered dose inhaler (MDI) 100/10 mcg twice daily (BID) for 14 days
MF/F MDI 200/10 mcg	MF/F MDI 200/10 mcg BID for 14 days
MF/F MDI 400/10 mcg	MF/F MDI 400/10 mcg BID for 14 days
MF DPI 200 mcg	Mometasone furoate (MF) dry powder inhaler (DPI) 200 mcg BID for 14 days
MF MDI 200 mcg	MF MDI 200 mcg BID for 14 days
Placebo	Placebo MDI BID for 14 days

Participant Flow: Overall Study

	MF/F MDI 100/10 mcg	MF/F MDI 200/10 mcg	MF/F MDI 400/10 mcg	MF DPI 200 mcg	MF MDI 200 mcg	Placebo
STARTED	**20**	**17**	**12**	**15**	**16**	**13**
COMPLETED	**19**	**17**	**12**	**15**	**16**	**13**
NOT COMPLETED	**1**	**0**	**0**	**0**	**0**	**0**
Protocol Violation	**1**	**0**	**0**	**0**	**0**	**0**

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.

No text entered.

Reporting Groups

	Description
MF/F MDI 100/10 mcg	Mometasone furoate/formoterol fumarate (MF/F) metered dose inhaler (MDI) 100/10 mcg twice daily (BID) for 14 days
MF/F MDI 200/10 mcg	MF/F MDI 200/10 mcg BID for 14 days
MF/F MDI 400/10 mcg	MF/F MDI 400/10 mcg BID for 14 days
MF DPI 200 mcg	Mometasone furoate (MF) dry powder inhaler (DPI) 200 mcg BID for 14 days
MF MDI 200 mcg	MF MDI 200 mcg BID for 14 days
Placebo	Placebo MDI BID for 14 days
Total	Total of all reporting groups

Baseline Measures

	MF/F MDI 100/10 mcg	MF/F MDI 200/10 mcg	MF/F MDI 400/10 mcg	MF DPI 200 mcg	MF MDI 200 mcg	Placebo	Total
Number of Participants [units: participants]	20	17	12	15	16	13	93
Age, Customized [units: participants]							
18 to <65 years	20	14	11	15	16	11	87
> or = to 65 years	0	3	1	0	0	2	6
Gender [units: participants]							
Female	13	10	4	6	6	8	47
Male	7	7	8	9	10	5	46

Outcome Measures

Hide All Outcome Measures

1. Primary: Mean Percent Change From Baseline to Day 14 in Exhaled Nitric Oxide (eNO) Parts Per Billion (Ppb) [Time Frame: Baseline to Day 14]

Measure Type	Primary
Measure Title	Mean Percent Change From Baseline to Day 14 in Exhaled Nitric Oxide (eNO) Parts Per Billion (Ppb)
Measure Description	No text entered.
Time Frame	Baseline to Day 14
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All Randomized Participants

Reporting Groups

	Description
MF/F MDI 100/10 mcg	Mometasone furoate/formoterol fumarate (MF/F) metered dose inhaler (MDI) 100/10 mcg twice daily (BID) for 14 days
MF/F MDI 200/10 mcg	MF/F MDI 200/10 mcg BID for 14 days
MF/F MDI 400/10 mcg	MF/F MDI 400/10 mcg BID for 14 days
MF DPI 200 mcg	Mometasone furoate (MF) dry powder inhaler (DPI) 200 mcg BID for 14 days
MF MDI 200 mcg	MF MDI 200 mcg BID for 14 days
Placebo	Placebo MDI BID for 14 days

Measured Values

	MF/F MDI 100/10 mcg	MF/F MDI 200/10 mcg	MF/F MDI 400/10 mcg	MF DPI 200 mcg	MF MDI 200 mcg	Placebo
Number of Participants Analyzed [units: participants]	**19**	**16**	**12**	**14**	**15**	**13**
Mean Percent Change From Baseline to Day 14 in Exhaled Nitric Oxide (eNO) Parts Per Billion (Ppb) [units: percentage of eNO] Mean (Standard Deviation)	**-35.3 (40.3)**	**-45.4 (40.3)**	**-61.4 (40.3)**	**-51.3 (40.3)**	**-46.1 (40.3)**	**0.1 (40.3)**

Statistical Analysis 1 for Mean Percent Change From Baseline to Day 14 in Exhaled Nitric Oxide (eNO) Parts Per Billion (Ppb)

Groups [1]	MF/F MDI 400/10 mcg vs. Placebo
Method [2]	ANCOVA
P Value [3]	<0.001

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Analysis of covariance (ANCOVA) model with treatment and baseline eNO as a covariate was used. Standard deviation is a Pooled Standard deviation from ANCOVA Model with treatment effect and baseline eNO as a covariate.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

Statistical Analysis 2 for Mean Percent Change From Baseline to Day 14 in Exhaled Nitric Oxide (eNO) Parts Per Billion (Ppb)

Groups [1]	MF/F MDI 200/10 mcg vs. Placebo
Method [2]	ANCOVA
P Value [3]	0.003

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	ANCOVA model with treatment and baseline eNO as a covariate was used. Standard deviation is a Pooled Standard deviation from ANCOVA Model with treatment effect and baseline eNO as a covariate.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

Statistical Analysis 3 for Mean Percent Change From Baseline to Day 14 in Exhaled Nitric Oxide (eNO) Parts Per Billion (Ppb)

Groups [1]	MF/F MDI 100/10 mcg vs. Placebo
Method [2]	ANCOVA

P Value [3]	0.018

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	ANCOVA model with treatment and baseline eNO as a covariate was used. Standard deviation is a Pooled Standard deviation from ANCOVA Model with treatment effect and baseline eNO as a covariate.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

2. Secondary: Mean Percent Change From Baseline to Day 7 in eNO Ppb [Time Frame: Baseline to Day 7]

Measure Type	Secondary
Measure Title	Mean Percent Change From Baseline to Day 7 in eNO Ppb
Measure Description	No text entered.
Time Frame	Baseline to Day 7
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All Randomized Participants

Reporting Groups

	Description
MF/F MDI 100/10 mcg	Mometasone furoate/formoterol fumarate (MF/F) metered dose inhaler (MDI) 100/10 mcg twice daily (BID) for 14 days
MF/F MDI 200/10 mcg	MF/F MDI 200/10 mcg BID for 14 days
MF/F MDI 400/10 mcg	MF/F MDI 400/10 mcg BID for 14 days
MF DPI 200 mcg	Mometasone furoate (MF) dry powder inhaler (DPI) 200 mcg BID for 14 days
MF MDI 200 mcg	MF MDI 200 mcg BID for 14 days
Placebo	Placebo MDI BID for 14 days

Measured Values

	MF/F MDI 100/10 mcg	**MF/F MDI 200/10 mcg**	**MF/F MDI 400/10 mcg**	**MF DPI 200 mcg**	**MF MDI 200 mcg**	**Placebo**
Number of Participants Analyzed [units: participants]	**19**	**16**	**12**	**14**	**15**	**13**
Mean Percent Change From Baseline to Day 7 in eNO Ppb [units: percentage of eNO]	**-37.9 (36.3)**	**-39.7 (36.3)**	**-45.6 (36.3)**	**-46.0 (36.3)**	**-37.2 (36.3)**	**4.8 (36.3)**

Mean (Standard Deviation)						

Statistical Analysis 1 for Mean Percent Change From Baseline to Day 7 in eNO Ppb

Groups [1]	MF/F MDI 400/10 mcg vs. Placebo
Method [2]	ANCOVA
P Value [3]	<0.001

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	ANCOVA model with treatment and baseline eNO as a covariate was used. Standard deviation is a Pooled Standard deviation from ANCOVA Model with treatment effect and baseline eNO as a covariate.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

Statistical Analysis 2 for Mean Percent Change From Baseline to Day 7 in eNO Ppb

Groups [1]	MF/F MDI 200/10 mcg vs. Placebo
Method [2]	ANCOVA
P Value [3]	0.002

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	ANCOVA model with treatment and baseline eNO as a covariate was used. Standard deviation is a Pooled Standard deviation from ANCOVA Model with treatment effect and baseline eNO as a covariate.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

Statistical Analysis 3 for Mean Percent Change From Baseline to Day 7 in eNO Ppb

Groups [1]	MF/F MDI 100/10 mcg vs. Placebo
Method [2]	ANCOVA
P Value [3]	0.002

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	ANCOVA model with treatment and baseline eNO as a covariate was used. Standard deviation is a Pooled Standard deviation from ANCOVA Model with treatment effect and baseline eNO as a covariate.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.

[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

3. Secondary: Mean Percent Change From Baseline to Day 14 in Sputum Eosinophil Count (Percentage) [Time Frame: Baseline to Day 14]

Measure Type	Secondary
Measure Title	Mean Percent Change From Baseline to Day 14 in Sputum Eosinophil Count (Percentage)
Measure Description	No text entered.
Time Frame	Baseline to Day 14
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All randomized participants

Reporting Groups

	Description
MF/F MDI 100/10 mcg	Mometasone furoate/formoterol fumarate (MF/F) metered dose inhaler (MDI) 100/10 mcg twice daily (BID) for 14 days
MF/F MDI 200/10 mcg	MF/F MDI 200/10 mcg BID for 14 days
MF/F MDI 400/10 mcg	MF/F MDI 400/10 mcg BID for 14 days
MF DPI 200 mcg	Mometasone furoate (MF) dry powder inhaler (DPI) 200 mcg BID for 14 days
MF MDI 200 mcg	MF MDI 200 mcg BID for 14 days
Placebo	Placebo MDI BID for 14 days

Measured Values

	MF/F MDI 100/10 mcg	**MF/F MDI 200/10 mcg**	**MF/F MDI 400/10 mcg**	**MF DPI 200 mcg**	**MF MDI 200 mcg**	**Placebo**
Number of Participants Analyzed [units: participants]	**15**	**13**	**7**	**12**	**11**	**10**
Mean Percent Change From Baseline to Day 14 in Sputum Eosinophil Count (Percentage) [units: percentage of Sputum Eosinophil Count] Mean (Standard Deviation)	**21.1 (127.6)**	**-35.5 (127.6)**	**-75.4 (127.6)**	**-55.3 (127.6)**	**-33.7 (127.6)**	**71.7 (127.6)**

Statistical Analysis 1 for Mean Percent Change From Baseline to Day 14 in Sputum Eosinophil Count (Percentage)

Groups [1]	MF/F MDI 400/10 mcg vs. Placebo
Method [2]	ANCOVA
[3]	0.024

P Value	

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	ANCOVA model with treatment and baseline eosinophils as a covariate was used. Standard deviation is a Pooled Standard deviation from ANCOVA Model with treatment effect and baseline EOS as a covariate.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

Statistical Analysis 2 for Mean Percent Change From Baseline to Day 14 in Sputum Eosinophil Count (Percentage)

Groups [1]	MF/F MDI 200/10 mcg vs. Placebo
Method [2]	ANCOVA
P Value [3]	0.051

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	ANCOVA model with treatment and baseline eosinophils as a covariate was used. Standard deviation is a Pooled Standard deviation from ANCOVA Model with treatment effect and baseline EOS as a covariate.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

Statistical Analysis 3 for Mean Percent Change From Baseline to Day 14 in Sputum Eosinophil Count (Percentage)

Groups [1]	MF/F MDI 100/10 mcg vs. Placebo
Method [2]	ANCOVA
P Value [3]	0.336

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	ANCOVA model with treatment and baseline eosinophils as a covariate was used. Standard deviation is a Pooled Standard deviation from ANCOVA Model with treatment effect and baseline EOS as a covariate.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

4. Secondary: Mean Change From Baseline to Day 15 of Mannitol Challenge [Time Frame: Baseline to Day 15]

Measure Type	Secondary
Measure Title	Mean Change From Baseline to Day 15 of Mannitol Challenge
Measure Description	Mannitol challenge (also referred to as PD15) is the provocative dose of mannitol required to produce a 15% reduction in the forced expiratory volume (in liters) in one second (FEV1).
Time Frame	Baseline to Day 15
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All randomized participants

Reporting Groups

	Description
MF/F MDI 100/10 mcg	Mometasone furoate/formoterol fumarate (MF/F) metered dose inhaler (MDI) 100/10 mcg twice daily (BID) for 14 days
MF/F MDI 200/10 mcg	MF/F MDI 200/10 mcg BID for 14 days
MF/F MDI 400/10 mcg	MF/F MDI 400/10 mcg BID for 14 days
MF DPI 200 mcg	Mometasone furoate (MF) dry powder inhaler (DPI) 200 mcg BID for 14 days
MF MDI 200 mcg	MF MDI 200 mcg BID for 14 days
Placebo	Placebo MDI BID for 14 days

Measured Values

	MF/F MDI 100/10 mcg	**MF/F MDI 200/10 mcg**	**MF/F MDI 400/10 mcg**	**MF DPI 200 mcg**	**MF MDI 200 mcg**	**Placebo**
Number of Participants Analyzed [units: participants]	**12**	**9**	**6**	**8**	**9**	**9**
Mean Change From Baseline to Day 15 of Mannitol Challenge [units: milligrams] Mean (Standard Deviation)						
Baseline	**102.2 (106.7)**	**48.6 (106.7)**	**67.9 (106.7)**	**137.6 (106.7)**	**126.0 (106.7)**	**159.4 (106.7)**
Mean Change from Baseline to Day 15	**176.6 (264)**	**153.8 (264)**	**162.9 (264)**	**159.4 (264)**	**146.2 (264)**	**-63.7 (264)**

Statistical Analysis 1 for Mean Change From Baseline to Day 15 of Mannitol Challenge

Groups [1]	MF/F MDI 400/10 mcg vs. Placebo
Method [2]	ANCOVA
P Value [3]	0.120

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	ANCOVA model with treatment and baseline PD15 as a covariate was used.

	Standard deviation is a Pooled Standard deviation from ANCOVA Model with treatment effect and baseline PD15 as a covariate.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Analysis applies to Mean Change from Baseline to Day 15.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

Statistical Analysis 2 for Mean Change From Baseline to Day 15 of Mannitol Challenge

Groups [1]	MF/F MDI 200/10 mcg vs. Placebo
Method [2]	ANCOVA
P Value [3]	0.103

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	ANCOVA model with treatment and baseline PD15 as a covariate was used. Standard deviation is a Pooled Standard deviation from ANCOVA Model with treatment effect and baseline PD15 as a covariate.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Analysis applies to Mean Change from Baseline to Day 15.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

Statistical Analysis 3 for Mean Change From Baseline to Day 15 of Mannitol Challenge

Groups [1]	MF/F MDI 100/10 mcg vs. Placebo
Method [2]	ANCOVA
P Value [3]	0.048

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	ANCOVA model with treatment and baseline PD15 as a covariate was used. Standard deviation is a Pooled Standard deviation from ANCOVA Model with treatment effect and baseline PD15 as a covariate.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Analysis applies to Mean Change from Baseline to Day 15.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

5. Secondary: Change From Baseline in AM Total Asthma Symptom Score at Days 2-15 [Time Frame: Baseline and Days 2-15]

Measure Type	Secondary
Measure Title	Change From Baseline in AM Total Asthma Symptom Score at Days 2-15

Measure Description	Twice daily, participants rated the following asthma symptoms as experienced during the time period since the last evaluation: wheezing, difficulty breathing, and cough on a scale of 0 (none) to 3 (severe, very uncomfortable and interfered with most or all of normal daily activities/sleep). The total asthma symptom score ranged from 0 to 9. The results were recorded in the participant's diary.
Time Frame	Baseline and Days 2-15
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All randomized participants

Reporting Groups

	Description
MF/F MDI 100/10 mcg	Mometasone furoate/formoterol fumarate (MF/F) metered dose inhaler (MDI) 100/10 mcg twice daily (BID) for 14 days
MF/F MDI 200/10 mcg	MF/F MDI 200/10 mcg BID for 14 days
MF/F MDI 400/10 mcg	MF/F MDI 400/10 mcg BID for 14 days
MF DPI 200 mcg	Mometasone furoate (MF) dry powder inhaler (DPI) 200 mcg BID for 14 days
MF MDI 200 mcg	MF MDI 200 mcg BID for 14 days
Placebo	Placebo MDI BID for 14 days

Measured Values

	MF/F MDI 100/10 mcg	**MF/F MDI 200/10 mcg**	**MF/F MDI 400/10 mcg**	**MF DPI 200 mcg**	**MF MDI 200 mcg**	**Placebo**
Number of Participants Analyzed [units: participants]	**20**	**17**	**12**	**15**	**16**	**13**
Change From Baseline in AM Total Asthma Symptom Score at Days 2-15 [units: units on a scale] Mean (Standard Deviation)						
Baseline	**1.6 (1.66)**	**1.2 (1.66)**	**2.2 (1.66)**	**1.5 (1.66)**	**1.1 (1.66)**	**1.4 (1.66)**
Mean Change from Baseline to Days 2-15	**-0.7 (1.28)**	**-0.7 (1.28)**	**-1.5 (1.28)**	**-1.2 (1.28)**	**-0.5 (1.28)**	**-0.2 (1.28)**

Statistical Analysis 1 for Change From Baseline in AM Total Asthma Symptom Score at Days 2-15

Groups [1]	MF/F MDI 400/10 mcg vs. Placebo
Method [2]	ANOVA
P Value [3]	0.018

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	One-way analysis of variance (ANOVA) model with treatment effect was used. Standard deviation is a Pooled Standard deviation from the one-way ANOVA model with treatment effect.

[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Analysis applies to Mean Change from Baseline to Days 2-15.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

Statistical Analysis 2 for Change From Baseline in AM Total Asthma Symptom Score at Days 2-15

Groups [1]	MF/F MDI 200/10 mcg vs. Placebo
Method [2]	ANOVA
P Value [3]	0.261

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	One-way ANOVA model with treatment effect was used. Standard deviation is a Pooled Standard deviation from the one-way ANOVA model with treatment effect.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Analysis applies to Mean Change from Baseline to Days 2-15.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

Statistical Analysis 3 for Change From Baseline in AM Total Asthma Symptom Score at Days 2-15

Groups [1]	MF/F MDI 100/10 mcg vs. Placebo
Method [2]	ANOVA
P Value [3]	0.334

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	One-way ANOVA model with treatment effect was used. Standard deviation is a Pooled Standard deviation from the one-way ANOVA model with treatment effect.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Analysis applies to Mean Change from Baseline to Days 2-15.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

6. Secondary: Change From Baseline in PM Total Asthma Symptom Score at Days 1-15 [Time Frame: Baseline and Days 1-15]

Measure Type	Secondary
Measure Title	Change From Baseline in PM Total Asthma Symptom Score at Days 1-15
Measure Description	Twice daily, participants rated the following asthma symptoms as experienced during the time period since the last evaluation: wheezing, difficulty breathing, and cough on a scale of 0 (none) to 3 (severe, very uncomfortable and

	interfered with most or all of normal daily activities/sleep). The total asthma symptom score ranged from 0 to 9. The results were recorded in the participant's diary.
Time Frame	Baseline and Days 1-15
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All randomized participants

Reporting Groups

	Description
MF/F MDI 100/10 mcg	Mometasone furoate/formoterol fumarate (MF/F) metered dose inhaler (MDI) 100/10 mcg twice daily (BID) for 14 days
MF/F MDI 200/10 mcg	MF/F MDI 200/10 mcg BID for 14 days
MF/F MDI 400/10 mcg	MF/F MDI 400/10 mcg BID for 14 days
MF DPI 200 mcg	Mometasone furoate (MF) dry powder inhaler (DPI) 200 mcg BID for 14 days
MF MDI 200 mcg	MF MDI 200 mcg BID for 14 days
Placebo	Placebo MDI BID for 14 days

Measured Values

	MF/F MDI 100/10 mcg	**MF/F MDI 200/10 mcg**	**MF/F MDI 400/10 mcg**	**MF DPI 200 mcg**	**MF MDI 200 mcg**	**Placebo**
Number of Participants Analyzed [units: participants]	**20**	**17**	**12**	**15**	**15**	**13**
Change From Baseline in PM Total Asthma Symptom Score at Days 1-15 [units: units on a scale] Mean (Standard Deviation)						
Baseline	**1.7 (1.62)**	**1.1 (1.62)**	**2.1 (1.62)**	**1.6 (1.62)**	**1.6 (1.62)**	**1.7 (1.62)**
Mean Change from Baseline to Days 1-15	**-0.4 (1.24)**	**-0.6 (1.24)**	**-1.4 (1.24)**	**-1.1 (1.24)**	**-0.7 (1.24)**	**-0.3 (1.24)**

Statistical Analysis 1 for Change From Baseline in PM Total Asthma Symptom Score at Days 1-15

Groups [1]	MF/F MDI 400/10 mcg vs. Placebo
Method [2]	ANOVA
P Value [3]	0.037

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	One-way ANOVA model with treatment effect was used. Standard deviation is a Pooled Standard deviation from the one-way ANOVA model with treatment effect.
[2]	Other relevant method information, such as adjustments or degrees of freedom:

	Analysis applies to Mean Change from Baseline to Days 1-15.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

Statistical Analysis 2 for Change From Baseline in PM Total Asthma Symptom Score at Days 1-15

Groups [1]	MF/F MDI 200/10 mcg vs. Placebo
Method [2]	ANOVA
P Value [3]	0.643

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	One-way ANOVA model with treatment effect was used. Standard deviation is a Pooled Standard deviation from the one-way ANOVA model with treatment effect.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Analysis applies to Mean Change from Baseline to Days 1-15.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

Statistical Analysis 3 for Change From Baseline in PM Total Asthma Symptom Score at Days 1-15

Groups [1]	MF/F MDI 100/10 mcg vs. Placebo
Method [2]	ANOVA
P Value [3]	0.963

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	One-way ANOVA model with treatment effect was used. Standard deviation is a Pooled Standard deviation from the one-way ANOVA model with treatment effect.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Analysis applies to Mean Change from Baseline to Days 1-15.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

7. Secondary: Change From Baseline in AM Peak Expiratory Flow (PEF) at Days 2-15 [Time Frame: Baseline and Days 2-15]

Measure Type	Secondary
Measure Title	Change From Baseline in AM Peak Expiratory Flow (PEF) at Days 2-15
Measure Description	No text entered.
Time Frame	Baseline and Days 2-15

Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All randomized participants

Reporting Groups

	Description
MF/F MDI 100/10 mcg	Mometasone furoate/formoterol fumarate (MF/F) metered dose inhaler (MDI) 100/10 mcg twice daily (BID) for 14 days
MF/F MDI 200/10 mcg	MF/F MDI 200/10 mcg BID for 14 days
MF/F MDI 400/10 mcg	MF/F MDI 400/10 mcg BID for 14 days
MF DPI 200 mcg	Mometasone furoate (MF) dry powder inhaler (DPI) 200 mcg BID for 14 days
MF MDI 200 mcg	MF MDI 200 mcg BID for 14 days
Placebo	Placebo MDI BID for 14 days

Measured Values

	MF/F MDI 100/10 mcg	**MF/F MDI 200/10 mcg**	**MF/F MDI 400/10 mcg**	**MF DPI 200 mcg**	**MF MDI 200 mcg**	**Placebo**
Number of Participants Analyzed [units: participants]	**20**	**17**	**12**	**15**	**16**	**13**
Change From Baseline in AM Peak Expiratory Flow (PEF) at Days 2-15 [units: liters/minute] Mean (Standard Deviation)						
Baseline	**452.6 (112.1)**	**421.2 (112.1)**	**468.7 (112.1)**	**466.3 (112.1)**	**473.3 (112.1)**	**413.2 (112.1)**
Mean Change from Baseline to Days 2-15	**48.1 (47.0)**	**46.9 (47.0)**	**69.8 (47.0)**	**30.3 (47.0)**	**30.8 (47.0)**	**-9.0 (47.0)**

Statistical Analysis 1 for Change From Baseline in AM Peak Expiratory Flow (PEF) at Days 2-15

Groups [1]	MF/F MDI 400/10 mcg vs. Placebo
Method [2]	ANOVA
P Value [3]	<0.001

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	One-way ANOVA model with treatment effect was used. Standard deviation is a Pooled Standard deviation from the one-way ANOVA model with treatment effect.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Analysis applies to Mean Change from Baseline to Days 2-15.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:

	No text entered.

Statistical Analysis 2 for Change From Baseline in AM Peak Expiratory Flow (PEF) at Days 2-15

Groups [1]	MF/F MDI 200/10 mcg vs. Placebo
Method [2]	ANOVA
P Value [3]	0.002

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	One-way ANOVA model with treatment effect was used. Standard deviation is a Pooled Standard deviation from the one-way ANOVA model with treatment effect.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Analysis applies to Mean Change from Baseline to Days 2-15.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

Statistical Analysis 3 for Change From Baseline in AM Peak Expiratory Flow (PEF) at Days 2-15

Groups [1]	MF/F MDI 100/10 mcg vs. Placebo
Method [2]	ANOVA
P Value [3]	<0.001

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	One-way ANOVA model with treatment effect was used. Standard deviation is a Pooled Standard deviation from the one-way ANOVA model with treatment effect.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Analysis applies to Mean Change from Baseline to Days 2-15.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

8. Secondary: Change From Baseline in PM PEF at Days 1-15 [Time Frame: Baseline and Days 1-15]

Measure Type	Secondary
Measure Title	Change From Baseline in PM PEF at Days 1-15
Measure Description	No text entered.
Time Frame	Baseline and Days 1-15
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or

another method. Also provides relevant details such as imputation technique, as appropriate.
All randomized participants

Reporting Groups

	Description
MF/F MDI 100/10 mcg	Mometasone furoate/formoterol fumarate (MF/F) metered dose inhaler (MDI) 100/10 mcg twice daily (BID) for 14 days
MF/F MDI 200/10 mcg	MF/F MDI 200/10 mcg BID for 14 days
MF/F MDI 400/10 mcg	MF/F MDI 400/10 mcg BID for 14 days
MF DPI 200 mcg	Mometasone furoate (MF) dry powder inhaler (DPI) 200 mcg BID for 14 days
MF MDI 200 mcg	MF MDI 200 mcg BID for 14 days
Placebo	Placebo MDI BID for 14 days

Measured Values

	MF/F MDI 100/10 mcg	MF/F MDI 200/10 mcg	MF/F MDI 400/10 mcg	MF DPI 200 mcg	MF MDI 200 mcg	Placebo
Number of Participants Analyzed [units: participants]	**20**	**17**	**12**	**15**	**15**	**13**
Change From Baseline in PM PEF at Days 1-15 [units: liters/minute] Mean (Standard Deviation)						
Baseline	**462.0 (114.6)**	**437.2 (114.6)**	**486.7 (114.6)**	**484.4 (114.6)**	**472.5 (114.6)**	**422.7 (114.6)**
Mean Change from Baseline to Days 1-15	**47.7 (42.3)**	**34.5 (42.3)**	**66.8 (42.3)**	**20.2 (42.3)**	**28.3 (42.3)**	**4.5 (42.3)**

Statistical Analysis 1 for Change From Baseline in PM PEF at Days 1-15

Groups [1]	MF/F MDI 400/10 mcg vs. Placebo
Method [2]	ANOVA
P Value [3]	<0.001

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	One-way ANOVA model with treatment effect was used. Standard deviation is a Pooled Standard deviation from the one-way ANOVA model with treatment effect.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Analysis applies to Mean Change from Baseline to Days 1-15.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

Statistical Analysis 2 for Change From Baseline in PM PEF at Days 1-15

Groups [1]	MF/F MDI 200/10 mcg vs. Placebo

Method [2]	ANOVA
P Value [3]	0.057

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	One-way ANOVA model with treatment effect was used. Standard deviation is a Pooled Standard deviation from the one-way ANOVA model with treatment effect.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Analysis applies to Mean Change from Baseline to Days 1-15.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

Statistical Analysis 3 for Change From Baseline in PM PEF at Days 1-15

Groups [1]	MF/F MDI 100/10 mcg vs. Placebo
Method [2]	ANOVA
P Value [3]	0.005

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	One-way ANOVA model with treatment effect was used. Standard deviation is a Pooled Standard deviation from the one-way ANOVA model with treatment effect.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Analysis applies to Mean Change from Baseline to Days 1-15.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

9. Other Pre-specified: Baseline Exhaled Nitric Oxide (eNO) Parts Per Billion (Ppb) [Time Frame: Baseline]

Measure Type	Other Pre-specified
Measure Title	Baseline Exhaled Nitric Oxide (eNO) Parts Per Billion (Ppb)
Measure Description	No text entered.
Time Frame	Baseline
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
MF/F MDI 100/10 mcg	Mometasone furoate/formoterol fumarate (MF/F) metered dose inhaler (MDI) 100/10 mcg twice daily (BID) for 14 days
MF/F MDI 200/10 mcg	MF/F MDI 200/10 mcg BID for 14 days
MF/F MDI 400/10 mcg	MF/F MDI 400/10 mcg BID for 14 days
MF DPI 200 mcg	Mometasone furoate (MF) dry powder inhaler (DPI) 200 mcg BID for 14 days
MF MDI 200 mcg	MF MDI 200 mcg BID for 14 days
Placebo	Placebo MDI BID for 14 days

Measured Values

	MF/F MDI 100/10 mcg	MF/F MDI 200/10 mcg	MF/F MDI 400/10 mcg	MF DPI 200 mcg	MF MDI 200 mcg	Placebo
Number of Participants Analyzed [units: participants]	**19**	**16**	**12**	**14**	**15**	**13**
Baseline Exhaled Nitric Oxide (eNO) Parts Per Billion (Ppb) [units: ppb] Mean (Standard Deviation)	**54.8 (40.8)**	**70.0 (40.8)**	**77.1 (40.8)**	**102.6 (40.8)**	**66.2 (40.8)**	**79.6 (40.8)**

No statistical analysis provided for Baseline Exhaled Nitric Oxide (eNO) Parts Per Billion (Ppb)

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Reporting Groups

	Description
MF/F MDI 100/10 MCG BID	No text entered.
MF/F MDI 200/10 MCG BID	No text entered.
MF/F MDI 400/10 MCG BID	No text entered.
MF DPI 200 MCG BID	No text entered.
MF MDI 200 MCG BID	No text entered.
PLACEBO	No text entered.

Serious Adverse Events

	MF/F MDI 100/10 MCG BID	MF/F MDI 200/10 MCG BID	MF/F MDI 400/10 MCG BID	MF DPI 200 MCG BID	MF MDI 200 MCG BID	PLACEBO
Total, serious adverse events						
# participants affected / at risk	**0/20 (0.00%)**	**0/17 (0.00%)**	**0/12 (0.00%)**	**0/15 (0.00%)**	**0/16 (0.00%)**	**0/13 (0.00%)**

Other Adverse Events

Hide Other Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
MF/F MDI 100/10 MCG BID	No text entered.
MF/F MDI 200/10 MCG BID	No text entered.
MF/F MDI 400/10 MCG BID	No text entered.
MF DPI 200 MCG BID	No text entered.
MF MDI 200 MCG BID	No text entered.
PLACEBO	No text entered.

Other Adverse Events

	MF/F MDI 100/10 MCG BID	MF/F MDI 200/10 MCG BID	MF/F MDI 400/10 MCG BID	MF DPI 200 MCG BID	MF MDI 200 MCG BID	PLACEBO
Total, other (not including serious) adverse events						
# participants affected / at risk	**2/20 (10.00%)**	**8/17 (47.06%)**	**1/12 (8.33%)**	**2/15 (13.33%)**	**6/16 (37.50%)**	**2/13 (15.38%)**
Ear and labyrinth disorders						
† 1						

EAR DISCOMFORT						
# participants affected / at risk	**0/20 (0.00%)**	**0/17 (0.00%)**	**0/12 (0.00%)**	**0/15 (0.00%)**	**1/16 (6.25%)**	**0/13 (0.00%)**
# events	**0**	**0**	**0**	**0**	**1**	**0**
Gastrointestinal disorders						
GASTROOESOPHAGEAL REFLUX DISEASE † 1						
# participants affected / at risk	**0/20 (0.00%)**	**0/17 (0.00%)**	**0/12 (0.00%)**	**0/15 (0.00%)**	**1/16 (6.25%)**	**0/13 (0.00%)**
# events	**0**	**0**	**0**	**0**	**1**	**0**
INGUINAL HERNIA † 1						
# participants affected / at risk	**0/20 (0.00%)**	**1/17 (5.88%)**	**0/12 (0.00%)**	**0/15 (0.00%)**	**0/16 (0.00%)**	**0/13 (0.00%)**
# events	**0**	**1**	**0**	**0**	**0**	**0**
General disorders						
PYREXIA † 1						
# participants affected / at risk	**0/20 (0.00%)**	**0/17 (0.00%)**	**0/12 (0.00%)**	**0/15 (0.00%)**	**1/16 (6.25%)**	**0/13 (0.00%)**
# events	**0**	**0**	**0**	**0**	**1**	**0**
Infections and infestations						
NASOPHARYNGITIS † 1						
# participants affected / at risk	**1/20 (5.00%)**	**2/17 (11.76%)**	**0/12 (0.00%)**	**0/15 (0.00%)**	**0/16 (0.00%)**	**0/13 (0.00%)**
# events	**1**	**2**	**0**	**0**	**0**	**0**
ORAL CANDIDIASIS † 1						
# participants affected / at risk	**0/20 (0.00%)**	**0/17 (0.00%)**	**1/12 (8.33%)**	**0/15 (0.00%)**	**0/16 (0.00%)**	**0/13 (0.00%)**
# events	**0**	**0**	**1**	**0**	**0**	**0**
UPPER RESPIRATORY TRACT INFECTION † 1						
# participants affected / at risk	**0/20 (0.00%)**	**0/17 (0.00%)**	**0/12 (0.00%)**	**1/15 (6.67%)**	**0/16 (0.00%)**	**0/13 (0.00%)**
# events	**0**	**0**	**0**	**1**	**0**	**0**
Injury, poisoning and procedural complications						
SPINAL CORD INJURY † 1						
# participants affected / at risk	**0/20 (0.00%)**	**0/17 (0.00%)**	**0/12 (0.00%)**	**1/15 (6.67%)**	**0/16 (0.00%)**	**0/13 (0.00%)**
# events	**0**	**0**	**0**	**1**	**0**	**0**
SUNBURN † 1						
# participants affected / at risk	**0/20 (0.00%)**	**0/17 (0.00%)**	**0/12 (0.00%)**	**0/15 (0.00%)**	**1/16 (6.25%)**	**0/13 (0.00%)**
# events	**0**	**0**	**0**	**0**	**1**	**0**
Nervous system disorders						
DIZZINESS † 1						
# participants affected / at risk	**0/20 (0.00%)**	**0/17 (0.00%)**	**0/12 (0.00%)**	**0/15 (0.00%)**	**2/16 (12.50%)**	**0/13 (0.00%)**
# events	**0**	**0**	**0**	**0**	**3**	**0**

HEADACHE † 1						
# participants affected / at risk	**0/20 (0.00%)**	**2/17 (11.76%)**	**0/12 (0.00%)**	**0/15 (0.00%)**	**0/16 (0.00%)**	**0/13 (0.00%)**
# events	**0**	**3**	**0**	**0**	**0**	**0**
Respiratory, thoracic and mediastinal disorders						
COUGH † 1						
# participants affected / at risk	**0/20 (0.00%)**	**1/17 (5.88%)**	**0/12 (0.00%)**	**0/15 (0.00%)**	**0/16 (0.00%)**	**1/13 (7.69%)**
# events	**0**	**1**	**0**	**0**	**0**	**1**
DRY THROAT † 1						
# participants affected / at risk	**0/20 (0.00%)**	**0/17 (0.00%)**	**0/12 (0.00%)**	**0/15 (0.00%)**	**1/16 (6.25%)**	**0/13 (0.00%)**
# events	**0**	**0**	**0**	**0**	**1**	**0**
DYSPHONIA † 1						
# participants affected / at risk	**0/20 (0.00%)**	**1/17 (5.88%)**	**0/12 (0.00%)**	**1/15 (6.67%)**	**0/16 (0.00%)**	**0/13 (0.00%)**
# events	**0**	**1**	**0**	**1**	**0**	**0**
NASAL CONGESTION † 1						
# participants affected / at risk	**1/20 (5.00%)**	**0/17 (0.00%)**	**0/12 (0.00%)**	**0/15 (0.00%)**	**1/16 (6.25%)**	**0/13 (0.00%)**
# events	**1**	**0**	**0**	**0**	**1**	**0**
OROPHARYNGEAL PAIN † 1						
# participants affected / at risk	**1/20 (5.00%)**	**2/17 (11.76%)**	**0/12 (0.00%)**	**0/15 (0.00%)**	**2/16 (12.50%)**	**1/13 (7.69%)**
# events	**1**	**2**	**0**	**0**	**2**	**1**
RHINITIS ALLERGIC † 1						
# participants affected / at risk	**0/20 (0.00%)**	**1/17 (5.88%)**	**0/12 (0.00%)**	**0/15 (0.00%)**	**0/16 (0.00%)**	**0/13 (0.00%)**
# events	**0**	**1**	**0**	**0**	**0**	**0**
THROAT IRRITATION † 1						
# participants affected / at risk	**0/20 (0.00%)**	**1/17 (5.88%)**	**0/12 (0.00%)**	**0/15 (0.00%)**	**0/16 (0.00%)**	**0/13 (0.00%)**
# events	**0**	**1**	**0**	**0**	**0**	**0**
Skin and subcutaneous tissue disorders						
PAIN OF SKIN † 1						
# participants affected / at risk	**0/20 (0.00%)**	**0/17 (0.00%)**	**0/12 (0.00%)**	**0/15 (0.00%)**	**1/16 (6.25%)**	**0/13 (0.00%)**
# events	**0**	**0**	**0**	**0**	**1**	**0**
PRURITUS † 1						
# participants affected / at risk	**0/20 (0.00%)**	**0/17 (0.00%)**	**0/12 (0.00%)**	**0/15 (0.00%)**	**1/16 (6.25%)**	**0/13 (0.00%)**
# events	**0**	**0**	**0**	**0**	**1**	**0**

† Events were collected by systematic assessment

1 Term from vocabulary, MedDRA 12.0

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data
No text entered.

More Information

Hide More Information

Certain Agreements:

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

There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

The agreement is:

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.

☑ **Restriction Description:**
The investigator agrees not to publish/present any interim results without prior

sponsor written consent. The investigator agrees to provide to the sponsor, 45 days prior to submission, review copies for publication that report any study results. The sponsor has the right to review and comment. If the parties disagree, investigator agrees to meet with the sponsor, prior to submission for publication, to discuss and resolve any such issues/disagreement.

Results Point of Contact:

Name/Title: Senior Vice President, Global Clinical Development
Organization: Merck Sharp & Dohme Corp.
e-mail: ClinicalTrialsDisclosure@merck.com

Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

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Responsible Party:	Merck Sharp & Dohme Corp.
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