Effects of Mometasone Furoate Dry Powder Inhaler, Fluticasone Propionate, and Montelukast on Bone Mineral Density in Asthmatics (Study P03418)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00394355

First received: October 31, 2006
Last updated: June 23, 2015
Last verified: June 2015
History of Changes

Full Text View | Tabular View | Study Results | Disclaimer | How to Read a Study Record

Purpose

This is a randomized, multi-center, parallel-group, active-controlled, double-blind study evaluating the effects of mometasone furoate (MF) dry powder inhaler (DPI) on bone mineral density (BMD) in subjects with asthma. The mean percent change in lumbar spine BMD from the averaged baseline value (the average of the two scan results prior to treatment) to the endpoint of treatment time point (the average of the last two valid post-baseline scan results during treatment) for the comparison of MF DPI 400 mcg daily in the evening versus montelukast (ML) 10 mg daily in the evening.

Condition	Intervention	Phase
Asthma	Drug: mometasone furoate dry powder inhaler Drug: fluticasone propionate hydrofluoroalkane (HFA) Drug: montelukast	Phase 4

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

Official Title: Comparative Study of the Effect of Two Doses of Mometasone Furoate Dry Powder Inhaler 200 mcg and 400 mcg QD PM, Fluticasone Propionate 250 mcg BID, and Montelukast 10 mg QD PM, on Bone Mineral Density in Adults With Asthma

Resource links provided by NLM:

MedlinePlus related topics: Bone Density Minerals

Drug Information available for: Fluticasone propionate Mometasone furoate Fluticasone Mometasone furoate monohydrate Montelukast sodium Montelukast Fluticasone furoate

U.S. FDA Resources

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

Primary Outcome Measures:

- Mean Percent Change in Lumbar Spine Bone Mineral Density (BMD) From the Averaged Baseline Value to the Endpoint of Treatment Time Point [Time Frame: Baseline and up to ~ one year of treatment] [Designated as safety issue: Yes]

  The averaged baseline value is the average of the two scan results prior to treatment. The endpoint of treatment time point is the average of the last two valid post baseline BMD scans during the treatment period carried forward.

Secondary Outcome Measures:

- Mean Percent Change in the Left Total Femur From the Averaged Baseline Value to the Averaged Value at the Endpoint of Treatment Time Point [Time Frame: Baseline and up to ~ one year of treatment] [Designated as safety issue: Yes]

  The averaged baseline value is the average of the two scan results prior to treatment. The endpoint of treatment time point is the average of the last two valid post baseline BMD scans during the treatment period carried forward.

- Mean Percent Change in the Femoral Neck BMD From the Averaged Baseline Value to the Averaged Value at the Endpoint of Treatment Time Point [Time Frame: Baseline and up to ~ one year of treatment] [Designated as safety issue: Yes]

  The averaged baseline value is the average of the two scan results prior to treatment. The endpoint of treatment time point is the average of the last two valid post baseline BMD scans during the treatment period carried forward.

- Summary of Change From Baseline to Endpoint in FEV1 (Forced Expiratory Volume in One Second). [Time Frame: Baseline and up to ~ one year of treatment] [Designated as safety issue: No]

  Mean percent change from Baseline (the last non-missing value prior to treatment) in pulmonary function test FEV1 from in-office visits and at Endpoint (last non-missing postbaseline value carried forward)

Enrollment:	566
Study Start Date:	September 2006
Study Completion Date:	October 2009
Primary Completion Date:	October 2009 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Group 1 MF DPI 400 mcg once a day (QD) in the evening (PM)	Drug: mometasone furoate dry powder inhaler 400 mcg MF DPI via a breath-actuated, dry-powder inhaler and a placebo tablet given by mouth once daily in the evening for 1 year. Other Name: Asmanex
Experimental: Group 2 MF DPI 200 mcg QD PM	Drug: mometasone furoate dry powder inhaler 200 mcg MF DPI via a breath-actuated, dry-powder inhaler and a placebo tablet given by mouth once daily in the evening for 1 year. Other Name: Asmanex
Active Comparator: Group 3 Fluticasone propionate (FP) metered dose inhaler (MDI) 250 mcg twice a day (BID)	Drug: fluticasone propionate hydrofluoroalkane (HFA) 250 mcg FP HFA given twice a day via a metered-dose inhaler and a placebo tablet given once daily in the evening for 1 year Other Name: Flovent HFA
Active Comparator: Group 4 ML 10 mg QD PM	Drug: montelukast 10 mg given once daily in the evening by mouth for 1 year. Other Name: Singulair

Eligibility

Ages Eligible for Study:	18 Years to 50 Years
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Informed consent, adhere to schedules.
- Inform usual treating medical doctor (MD) of study participation.
- Female 18 to 40, male 18 to 50, any race.
- >=3-month asthma history.
- Never treated with inhaled corticosteroids (ICS) for asthma or not have taken ICS for ≥3 months prior to Screening.
- Prebronchodilator forced expiratory volume (liters) in 1 second (FEV1) >=60% & <=90% predicted at both Screening & Baseline, when all restricted medications withheld.
- Prior to randomization, demonstrate increase in absolute FEV1 of >=12%, with absolute volume increase of >=200 mL, after reversibility testing.
- Lab tests normal/acceptable to investigator/sponsor. Electrocardiogram (ECG) performed at screening or <30 days of screening normal/acceptable to investigator. Chest x-ray performed at screening or <12 months of screening normal/acceptable to investigator.
- 25-hydroxy vitamin D level >=15 ng/mL. If <15, re-tested after taking calcium plus vitamin D for 4 weeks.
- Free of significant disease (other than asthma) known to affect bone mineral metabolism including renal disease, unstable hyperthyroidism or other endocrinopathies, Paget's disease, osteoporosis, malabsorption, or others that could interfere with study evaluations (eg scoliosis, metal pins, calcification in spine/femur).
- Women of childbearing potential must use birth control. Includes: hormonal contraceptive, intra-uterine device (IUD); condom in combination with spermicide; monogamous relationship with male who had vasectomy or is using condom. Started method ≥3 months prior to Screening (exception condom), & agree to continue for duration. Women who are not currently sexually active must agree/consent to using double-barrier method if become active. Females must have negative serum pregnancy test at Screening.
- 2 valid scans, as confirmed by local dual energy x-ray absorptiometry (DXA) center, for lumbar spine, left total femur, & femoral neck prior to randomization. Valid scans will be 2 scans of same region, performed on same day, that agree within 5% & scans are technically satisfactory (eg correct scan mode, no artifacts present, correct region).

Exclusion Criteria:

- >12 inhalations/day of salbutamol on 2 consecutive days between Screening & Baseline.
- Increase/decrease in FEV1 of >=20% between Screening & Baseline.
- Treated with methotrexate, cyclosporin, gold, or other cytotoxic agents, for asthma or concurrent condition within last 3 months.
- Pipe/cigar smoking history.
- Smoker/ex-smoker who smoked within previous year or has smoking history ≥10 pack-years.
- Upper/lower respiratory tract infection within 2 weeks prior to Screening & Baseline. Can be rescheduled.
- >14 days of oral steroids within previous 12 months or required burst of systemic steroids within previous month.
- Ever required ventilator support for respiratory failure secondary to asthma.
- Treated in emergency room (ER) for asthma exacerbation or admitted to hospital for management of airway obstruction on 1 occasion in last 3 months or on >=2 occasions within last 6 months.
- Chronic bronchitis, bronchiectasis, emphysema or cystic fibrosis.
- Participated in study within last 30 days.
- Allergic to/intolerant of ICS, beta-agonists, or drugs/excipients in study.
- Average of 2 lumbar spine (L1-L4) scans at Screening is >2 standard deviations below normal.
- Condition that might affect ability to ambulate normally, (ie major surgical procedure). Condition that may interfere with BMD measurement.
- History of renal, hepatic, cardiovascular, metabolic, neurologic, hematologic, respiratory, gastrointestinal, cerebrovascular, or other which could interfere with study or require treatment which might interfere (eg calcium urolithiasis or absorptive hypercalcuria, insulin dependent diabetes, cancer within last 10 years (except basal cell carcinoma), active hepatitis, coronary artery disease, stroke, rheumatoid arthritis, human immunodeficiency virus (HIV), or respiratory conditions such as chronic obstructive pulmonary disease (COPD), chronic bronchitis, cystic fibrosis. Others which are well-controlled & stable (eg hypertension, arrhythmia, subjects on stable thyroid hormone replacement for at least 3 months whose thyroid stimulating hormone (TSH) levels are normal) may be allowed.
- Treated within last year with drug known to interfere with bone metabolism including: bisphosphonates, estrogens such as depot injectables (estrogens used in oral combined hormonal contraceptives are allowed if dose is stable throughout), high-dose fluoride, & thyroid replacement hormones (if not stabilized).
- History &/or presence of intraocular pressure in either eye >=22 mm Hg, glaucoma, &/or posterior subcapsular cataracts. History &/or presence of nuclear cataract or undergone bilateral lens extraction may be eligible.

The subject has undergone incisional or intraocular surgery in which the natural lens is still present in the eye.

- The subject has a history of penetrating trauma to both eyes.
- The subject has one or more of the following lens opacities classification system version III (LOCS III) grades at screening: nuclear opalescence (NO) >=3.0, nuclear color (NC) >=3.0, cortical (C) >=2.0, posterior (P) >=0.5.
- Pregnant, breast-feeding, or postmenopausal women. Amenorrhea >6 months will be excluded (exception hysterectomy). Bilateral oophorectomy excluded.
- Relevant abnormal Baseline vital sign.
- Body mass index (BMI) >35 kg/m2.
- HIV positive (testing not performed).
- Alcoholic or illicit drug abuser.
- Evidence of oropharyngeal candidiasis at Baseline with or without treatment. If evidence at Screening, may be treated as appropriate & visit can be scheduled upon resolution. If evidence at Baseline Visit, may be treated as appropriate & visit can be rescheduled upon resolution.
- Normal sleep/wake cycle is inverted (eg night shift workers).
- Taken restricted medications prior to Screening.
- Cannot adhere to prohibited & permitted concomitant medications.
- No subject may participate in this same study at another site or simultaneously in any other study.
- No person directly associated with administration of study may participate.

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:

Maspero J, Backer V, Yao R, Staudinger H, Teper A. Effects of mometasone, fluticasone, and montelukast on bone mineral density in adults with asthma. J Allergy Clin Immunol Pract. 2013 Nov-Dec;1(6):649-55.e1. doi: 10.1016/j.jaip.2013.07.011. Epub 2013 Oct 8.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00394355 History of Changes
Other Study ID Numbers:	P03418 Doc ID: 3387777; EUDRACT No: 2004-002930-21;
Study First Received:	October 31, 2006
Results First Received:	October 22, 2010
Last Updated:	June 23, 2015
Health Authority:	Argentina: Administracion Nacional de Medicamentos, Alimentos y Tecnologia Medica

Additional relevant MeSH terms:

Fluticasone	Hormone Antagonists
Mometasone furoate	Hormones, Hormone Substitutes, and Hormone Antagonists
Montelukast	Leukotriene Antagonists
Anti-Allergic Agents	Peripheral Nervous System Agents
Anti-Asthmatic Agents	Pharmacologic Actions
Anti-Inflammatory Agents	Physiological Effects of Drugs
Autonomic Agents	Respiratory System Agents
Bronchodilator Agents	Therapeutic Uses
Dermatologic Agents	

ClinicalTrials.gov processed this record on May 08, 2016

TO TOP

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First received: October 31, 2006
Last updated: June 23, 2015
Last verified: June 2015
History of Changes

Results First Received: October 22, 2010

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Treatment
Condition:	Asthma
Interventions:	Drug: mometasone furoate dry powder inhaler Drug: fluticasone propionate hydrofluoroalkane (HFA) Drug: montelukast

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 DPI 200 mcg QD PM	Mometasone furoate (MF) dry powder inhaler (DPI) 200 mcg once daily (QD) in the evening (PM) for 1 year
MF DPI 400 mcg QD PM	MF DPI 400 mcg QD PM for 1 year
FP MDI 250 mcg BID	Fluticasone proprionate (FP) metered dose inhaler (MDI) 250 mcg twice daily (BID) for 1 year
ML 10 mg QD PM	Montelukast (ML) 10 mg QD PM for 1 year

Participant Flow: Overall Study

	MF DPI 200 mcg QD PM	MF DPI 400 mcg QD PM	FP MDI 250 mcg BID	ML 10 mg QD PM
STARTED	**140**	**137**	**147**	**142**
COMPLETED	**105**	**103**	**109**	**111**
NOT COMPLETED	**35**	**34**	**38**	**31**
Adverse Event	**10**	**6**	**7**	**8**
Did not meet protocol eligibility	**1**	**5**	**4**	**2**
Subject withdrawal - unrelated to drug	**12**	**14**	**10**	**6**
Subject withdrawal - related to drug	**1**	**0**	**0**	**0**
Lost to Follow-up	**7**	**5**	**4**	**3**
Noncompliance with protocol	**4**	**3**	**10**	**8**
Administrative	**0**	**1**	**1**	**1**
Lack of Efficacy	**0**	**0**	**2**	**3**

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 DPI 200 mcg QD PM	Mometasone furoate (MF) dry powder inhaler (DPI) 200 mcg once daily (QD) in the evening (PM) for 1 year
MF DPI 400 mcg QD PM	MF DPI 400 mcg QD PM for 1 year
FP MDI 250 mcg BID	Fluticasone proprionate (FP) metered dose inhaler (MDI) 250 mcg twice daily (BID) for 1 year
ML 10 mg QD PM	Montelukast (ML) 10 mg QD PM for 1 year
Total	Total of all reporting groups

Baseline Measures

	MF DPI 200 mcg QD	MF DPI 400 mcg QD	FP MDI 250 mcg BID	ML 10 mg QD PM	Total

	PM	PM			
Number of Participants [units: participants]	140	137	147	142	566
Age [units: years] Mean (Standard Deviation)	29.7 (7.8)	29.8 (8.1)	28.2 (6.9)	28.2 (7.1)	29.0 (7.5)
Gender [units: participants]					
Female	91	90	90	88	359
Male	49	47	57	54	207

Outcome Measures

Hide All Outcome Measures

1. Primary: Mean Percent Change in Lumbar Spine Bone Mineral Density (BMD) From the Averaged Baseline Value to the Endpoint of Treatment Time Point [Time Frame: Baseline and up to ~ one year of treatment]

Measure Type	Primary
Measure Title	Mean Percent Change in Lumbar Spine Bone Mineral Density (BMD) From the Averaged Baseline Value to the Endpoint of Treatment Time Point
Measure Description	The averaged baseline value is the average of the two scan results prior to treatment. The endpoint of treatment time point is the average of the last two valid post baseline BMD scans during the treatment period carried forward.
Time Frame	Baseline and up to ~ one year of treatment
Safety Issue	Yes

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 DPI 200 mcg QD PM	Mometasone furoate (MF) dry powder inhaler (DPI) 200 mcg once daily (QD) in the evening (PM) for 1 year
MF DPI 400 mcg QD PM	MF DPI 400 mcg QD PM for 1 year
FP MDI 250 mcg BID	Fluticasone proprionate (FP) metered dose inhaler (MDI) 250 mcg twice daily (BID) for 1 year
ML 10 mg QD PM	Montelukast (ML) 10 mg QD PM for 1 year

Measured Values

	MF DPI 200 mcg QD PM	MF DPI 400 mcg QD PM	FP MDI 250 mcg BID	ML 10 mg QD PM
Number of Participants Analyzed [units: participants]	117	121	131	127

Mean Percent Change in Lumbar Spine Bone Mineral Density (BMD) From the Averaged Baseline Value to the Endpoint of Treatment Time Point [units: percentage of BMD] Mean (Standard Deviation)	**0.7 (2.56)**	**0.9 (2.56)**	**1.1 (2.56)**	**1.2 (2.56)**

Statistical Analysis 1 for Mean Percent Change in Lumbar Spine Bone Mineral Density (BMD) From the Averaged Baseline Value to the Endpoint of Treatment Time Point

Groups [1]	MF DPI 400 mcg QD PM vs. ML 10 mg QD PM
Method [2]	ANOVA
P Value [3]	0.261

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Least squares mean percent changes were obtained from the two-way analysis of variance (ANOVA) model with treatment and BMD scan center effects. Results shown use percent change as a response. Pooled Standard deviation from the ANOVA model with treatment effects.
[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 in Lumbar Spine Bone Mineral Density (BMD) From the Averaged Baseline Value to the Endpoint of Treatment Time Point

Groups [1]	FP MDI 250 mcg BID vs. ML 10 mg QD PM
Method [2]	ANOVA
P Value [3]	0.644

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Least squares mean percent changes were obtained from the two-way ANOVA model with treatment and BMD scan center effects. Results shown use percent change as a response. Pooled Standard deviation from the ANOVA model with treatment effects.
[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 in the Left Total Femur From the Averaged Baseline Value to the Averaged Value at the Endpoint of Treatment Time Point [Time Frame: Baseline and up to ~ one year of treatment]

Measure Type	Secondary
Measure Title	Mean Percent Change in the Left Total Femur From the Averaged Baseline Value to the Averaged Value at the Endpoint

	of Treatment Time Point
Measure Description	The averaged baseline value is the average of the two scan results prior to treatment. The endpoint of treatment time point is the average of the last two valid post baseline BMD scans during the treatment period carried forward.
Time Frame	Baseline and up to ~ one year of treatment
Safety Issue	Yes

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 DPI 200 mcg QD PM	Mometasone furoate (MF) dry powder inhaler (DPI) 200 mcg once daily (QD) in the evening (PM) for 1 year
MF DPI 400 mcg QD PM	MF DPI 400 mcg QD PM for 1 year
FP MDI 250 mcg BID	Fluticasone proprionate (FP) metered dose inhaler (MDI) 250 mcg twice daily (BID) for 1 year
ML 10 mg QD PM	Montelukast (ML) 10 mg QD PM for 1 year

Measured Values

	MF DPI 200 mcg QD PM	**MF DPI 400 mcg QD PM**	**FP MDI 250 mcg BID**	**ML 10 mg QD PM**
Number of Participants Analyzed [units: participants]	**117**	**121**	**130**	**127**
Mean Percent Change in the Left Total Femur From the Averaged Baseline Value to the Averaged Value at the Endpoint of Treatment Time Point [units: percentage of BMD] Mean (Standard Deviation)	**0.3 (2.00)**	**0.2 (2.00)**	**0.2 (2.00)**	**0.5 (2.00)**

Statistical Analysis 1 for Mean Percent Change in the Left Total Femur From the Averaged Baseline Value to the Averaged Value at the Endpoint of Treatment Time Point

Groups [1]	MF DPI 400 mcg QD PM vs. ML 10 mg QD PM
Method [2]	ANOVA
P Value [3]	0.359

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Least squares mean percent changes were obtained from the two-way ANOVA model with treatment and BMD scan center effects. Results shown use percent change as a response. Pooled Standard deviation from the ANOVA model with treatment effects.
[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 in the Left Total Femur From the Averaged Baseline Value to the Averaged Value at the Endpoint of Treatment Time Point

Groups [1]	FP MDI 250 mcg BID vs. ML 10 mg QD PM
Method [2]	ANOVA
P Value [3]	0.390

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Least squares mean percent changes were obtained from the two-way ANOVA model with treatment and BMD scan center effects. Results shown use percent change as a response. Pooled Standard deviation from the ANOVA model with treatment effects.
[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 in the Femoral Neck BMD From the Averaged Baseline Value to the Averaged Value at the Endpoint of Treatment Time Point [Time Frame: Baseline and up to ~ one year of treatment]

Measure Type	Secondary
Measure Title	Mean Percent Change in the Femoral Neck BMD From the Averaged Baseline Value to the Averaged Value at the Endpoint of Treatment Time Point
Measure Description	The averaged baseline value is the average of the two scan results prior to treatment. The endpoint of treatment time point is the average of the last two valid post baseline BMD scans during the treatment period carried forward.
Time Frame	Baseline and up to ~ one year of treatment
Safety Issue	Yes

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 DPI 200 mcg QD PM	Mometasone furoate (MF) dry powder inhaler (DPI) 200 mcg once daily (QD) in the evening (PM) for 1 year
MF DPI 400 mcg QD PM	MF DPI 400 mcg QD PM for 1 year
FP MDI 250 mcg BID	Fluticasone proprionate (FP) metered dose inhaler (MDI) 250 mcg twice daily (BID) for 1 year
ML 10 mg QD PM	Montelukast (ML) 10 mg QD PM for 1 year

Measured Values

	MF DPI 200 mcg QD PM	MF DPI 400 mcg QD PM	FP MDI 250 mcg BID	ML 10 mg QD PM
Number of Participants Analyzed [units: participants]	**117**	**121**	**130**	**127**
Mean Percent Change in the Femoral Neck BMD From the Averaged Baseline Value to the Averaged Value at the Endpoint of Treatment Time Point [units: percentage of BMD] Mean (Standard Deviation)	**-0.2 (3.17)**	**0.4 (3.17)**	**-0.4 (3.17)**	**-0.2 (3.17)**

Statistical Analysis 1 for Mean Percent Change in the Femoral Neck BMD From the Averaged Baseline Value to the Averaged Value at the Endpoint of Treatment Time Point

Groups [1]	MF DPI 400 mcg QD PM vs. ML 10 mg QD PM
Method [2]	ANOVA
P Value [3]	0.169

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Least squares mean percent changes were obtained from the two-way ANOVA model with treatment and BMD scan center effects. Results shown use percent change as a response. Pooled Standard deviation from the ANOVA model with treatment effects.
[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 in the Femoral Neck BMD From the Averaged Baseline Value to the Averaged Value at the Endpoint of Treatment Time Point

Groups [1]	FP MDI 250 mcg BID vs. ML 10 mg QD PM
Method [2]	ANOVA
P Value [3]	0.526

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Least squares mean percent changes were obtained from the two-way ANOVA model with treatment and BMD scan center effects. Results shown use percent change as a response. Pooled Standard deviation from the ANOVA model with treatment effects.
[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: Summary of Change From Baseline to Endpoint in FEV1 (Forced Expiratory Volume in One Second). [Time Frame: Baseline and up to ~ one year of treatment]

Measure Type	Secondary
Measure Title	Summary of Change From Baseline to Endpoint in FEV1 (Forced Expiratory Volume in One Second).
Measure Description	Mean percent change from Baseline (the last non-missing value prior to treatment) in pulmonary function test FEV1 from in-office visits and at Endpoint (last non-missing postbaseline value carried forward)
Time Frame	Baseline and up to ~ one year of treatment
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 DPI 200 mcg QD PM	Mometasone furoate (MF) dry powder inhaler (DPI) 200 mcg once daily (QD) in the evening (PM) for 1 year
MF DPI 400 mcg QD PM	MF DPI 400 mcg QD PM for 1 year
FP MDI 250 mcg BID	Fluticasone proprionate (FP) metered dose inhaler (MDI) 250 mcg twice daily (BID) for 1 year
ML 10 mg QD PM	Montelukast (ML) 10 mg QD PM for 1 year

Measured Values

	MF DPI 200 mcg QD PM	**MF DPI 400 mcg QD PM**	**FP MDI 250 mcg BID**	**ML 10 mg QD PM**
Number of Participants Analyzed [units: participants]	**140**	**136**	**146**	**141**
Summary of Change From Baseline to Endpoint in FEV1 (Forced Expiratory Volume in One Second). [units: percentage of FEV1] Mean (Standard Deviation)	**0.29 (0.43)**	**0.38 (0.43)**	**0.31 (0.43)**	**0.19 (0.43)**

Statistical Analysis 1 for Summary of Change From Baseline to Endpoint in FEV1 (Forced Expiratory Volume in One Second).

Groups [1]	MF DPI 400 mcg QD PM vs. ML 10 mg QD PM
Method [2]	ANOVA
P Value [3]	<0.001

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Least square means and Pstd (pooled standard deviations) are obtained from the ANOVA model with treatment effects.
[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 Summary of Change From Baseline to Endpoint in FEV1 (Forced Expiratory Volume in One Second).

Groups [1]	FP MDI 250 mcg BID vs. ML 10 mg QD PM
Method [2]	ANOVA
P Value [3]	0.023

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Least square means and Pstd (pooled standard deviations) are obtained from the ANOVA model with treatment effects.
[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.

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
MF DPI 200 mcg QD PM	Mometasone furoate (MF) dry powder inhaler (DPI) 200 mcg once daily (QD) in the evening (PM) for 1 year
MF DPI 400 mcg QD PM	MF DPI 400 mcg QD PM for 1 year
FP MDI 250 mcg BID	Fluticasone proprionate (FP) metered dose inhaler (MDI) 250 mcg twice daily (BID) for 1 year
ML 10 mg QD PM	Montelukast (ML) 10 mg QD PM for 1 year

Serious Adverse Events

	MF DPI 200 mcg QD PM	MF DPI 400 mcg QD PM	FP MDI 250 mcg BID	ML 10 mg QD PM
Total, serious adverse events				
# participants affected / at risk	**5/140 (3.57%)**	**2/137 (1.46%)**	**4/147 (2.72%)**	**8/142 (5.63%)**
Eye disorders				
Lenticular opacities [1]				
# participants affected / at risk	**0/140 (0.00%)**	**1/137 (0.73%)**	**0/147 (0.00%)**	**0/142 (0.00%)**
# events	**0**	**1**	**0**	**0**
Gastrointestinal disorders				

Gastritis [1]				
# participants affected / at risk	**1/140 (0.71%)**	**0/137 (0.00%)**	**0/147 (0.00%)**	**0/142 (0.00%)**
# events	**1**	**0**	**0**	**0**
Hepatobiliary disorders				
Cholelithiasis [1]				
# participants affected / at risk	**1/140 (0.71%)**	**0/137 (0.00%)**	**0/147 (0.00%)**	**0/142 (0.00%)**
# events	**1**	**0**	**0**	**0**
Infections and infestations				
Appendicitis [1]				
# participants affected / at risk	**0/140 (0.00%)**	**0/137 (0.00%)**	**0/147 (0.00%)**	**1/142 (0.70%)**
# events	**0**	**0**	**0**	**1**
Bronchopneumonia [1]				
# participants affected / at risk	**0/140 (0.00%)**	**0/137 (0.00%)**	**1/147 (0.68%)**	**0/142 (0.00%)**
# events	**0**	**0**	**1**	**0**
Herpes zoster [1]				
# participants affected / at risk	**0/140 (0.00%)**	**0/137 (0.00%)**	**0/147 (0.00%)**	**1/142 (0.70%)**
# events	**0**	**0**	**0**	**1**
Keratitis herpetic [1]				
# participants affected / at risk	**0/140 (0.00%)**	**0/137 (0.00%)**	**0/147 (0.00%)**	**1/142 (0.70%)**
# events	**0**	**0**	**0**	**1**
Pneumonia [1]				
# participants affected / at risk	**0/140 (0.00%)**	**0/137 (0.00%)**	**0/147 (0.00%)**	**1/142 (0.70%)**
# events	**0**	**0**	**0**	**1**
Injury, poisoning and procedural complications				
Drug exposure during pregnancy [1]				
# participants affected / at risk	**2/140 (1.43%)**	**0/137 (0.00%)**	**1/147 (0.68%)**	**1/142 (0.70%)**
# events	**2**	**0**	**1**	**1**
Overdose [1]				
# participants affected / at risk	**1/140 (0.71%)**	**0/137 (0.00%)**	**0/147 (0.00%)**	**0/142 (0.00%)**
# events	**1**	**0**	**0**	**0**
Pregnancy, puerperium and perinatal conditions				
Abortion spontaneous [1]				
# participants affected / at risk	**2/140 (1.43%)**	**0/137 (0.00%)**	**1/147 (0.68%)**	**1/142 (0.70%)**
# events	**2**	**0**	**1**	**1**
Ectopic pregnancy [1]				
# participants affected / at risk	**0/140 (0.00%)**	**0/137 (0.00%)**	**1/147 (0.68%)**	**0/142 (0.00%)**
# events	**0**	**0**	**1**	**0**
Psychiatric disorders				
Anxiety [1]				
# participants affected / at risk	**1/140 (0.71%)**	**0/137 (0.00%)**	**0/147 (0.00%)**	**0/142 (0.00%)**
# events	**1**	**0**	**0**	**0**
Depression [1]				

# participants affected / at risk	1/140 (0.71%)	0/137 (0.00%)	0/147 (0.00%)	0/142 (0.00%)
# events	1	0	0	0
Psychotic disorder [1]				
# participants affected / at risk	0/140 (0.00%)	0/137 (0.00%)	0/147 (0.00%)	1/142 (0.70%)
# events	0	0	0	1
Suicidal ideation [1]				
# participants affected / at risk	1/140 (0.71%)	0/137 (0.00%)	0/147 (0.00%)	0/142 (0.00%)
# events	1	0	0	0
Reproductive system and breast disorders				
Vaginal haemorrhage [1]				
# participants affected / at risk	0/140 (0.00%)	0/137 (0.00%)	0/147 (0.00%)	1/142 (0.70%)
# events	0	0	0	1
Respiratory, thoracic and mediastinal disorders				
Acute respiratory failure [1]				
# participants affected / at risk	1/140 (0.71%)	0/137 (0.00%)	0/147 (0.00%)	0/142 (0.00%)
# events	1	0	0	0
Asthma [1]				
# participants affected / at risk	0/140 (0.00%)	0/137 (0.00%)	0/147 (0.00%)	1/142 (0.70%)
# events	0	0	0	1
Asthmatic crisis [1]				
# participants affected / at risk	0/140 (0.00%)	1/137 (0.73%)	0/147 (0.00%)	0/142 (0.00%)
# events	0	1	0	0
Nasal septum deviation [1]				
# participants affected / at risk	0/140 (0.00%)	0/137 (0.00%)	1/147 (0.68%)	0/142 (0.00%)
# events	0	0	1	0
Pleural effusion [1]				
# participants affected / at risk	0/140 (0.00%)	0/137 (0.00%)	0/147 (0.00%)	1/142 (0.70%)
# events	0	0	0	1
Sinus congestion [1]				
# participants affected / at risk	0/140 (0.00%)	0/137 (0.00%)	1/147 (0.68%)	0/142 (0.00%)
# events	0	0	1	0
Social circumstances				
Victim of homicide [1]				
# participants affected / at risk	0/140 (0.00%)	0/137 (0.00%)	0/147 (0.00%)	1/142 (0.70%)
# events	0	0	0	1

1 Term from vocabulary, MedDRA 12.1

Other Adverse Events

Hide Other Adverse Events

Time Frame	No text entered.
Additional Description	No text

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Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
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Other Adverse Events

	MF DPI 200 mcg QD PM	MF DPI 400 mcg QD PM	FP MDI 250 mcg BID	ML 10 mg QD PM
Total, other (not including serious) adverse events				
# participants affected / at risk	**61/140 (43.57%)**	**69/137 (50.36%)**	**75/147 (51.02%)**	**64/142 (45.07%)**
Gastrointestinal disorders				
Abdominal pain [1]				
# participants affected / at risk	**5/140 (3.57%)**	**4/137 (2.92%)**	**8/147 (5.44%)**	**6/142 (4.23%)**
# events	**6**	**5**	**28**	**7**
Dyspepsia [1]				
# participants affected / at risk	**4/140 (2.86%)**	**7/137 (5.11%)**	**2/147 (1.36%)**	**2/142 (1.41%)**
# events	**12**	**8**	**3**	**3**
Infections and infestations				
Bronchitis [1]				
# participants affected / at risk	**3/140 (2.14%)**	**10/137 (7.30%)**	**7/147 (4.76%)**	**10/142 (7.04%)**
# events	**4**	**12**	**8**	**13**
Influenza [1]				
# participants affected / at risk	**14/140 (10.00%)**	**10/137 (7.30%)**	**11/147 (7.48%)**	**13/142 (9.15%)**
# events	**16**	**15**	**13**	**19**
Nasopharyngitis [1]				
# participants affected / at risk	**16/140 (11.43%)**	**27/137 (19.71%)**	**26/147 (17.69%)**	**23/142 (16.20%)**
# events	**29**	**45**	**40**	**32**
Pharyngitis [1]				
# participants affected / at risk	**17/140 (12.14%)**	**14/137 (10.22%)**	**11/147 (7.48%)**	**12/142 (8.45%)**
# events	**19**	**19**	**15**	**15**
Rhinitis [1]				
# participants affected / at risk	**3/140 (2.14%)**	**6/137 (4.38%)**	**3/147 (2.04%)**	**9/142 (6.34%)**
# events	**4**	**28**	**6**	**21**
Upper respiratory tract infection [1]				

# participants affected / at risk	**6/140 (4.29%)**	**10/137 (7.30%)**	**7/147 (4.76%)**	**2/142 (1.41%)**
# events	**9**	**15**	**7**	**2**
Musculoskeletal and connective tissue disorders				
Back pain [1]				
# participants affected / at risk	**4/140 (2.86%)**	**10/137 (7.30%)**	**9/147 (6.12%)**	**4/142 (2.82%)**
# events	**4**	**14**	**11**	**6**
Nervous system disorders				
Headache [1]				
# participants affected / at risk	**22/140 (15.71%)**	**18/137 (13.14%)**	**19/147 (12.93%)**	**21/142 (14.79%)**
# events	**55**	**38**	**37**	**93**
Respiratory, thoracic and mediastinal disorders				
Rhinitis allergic [1]				
# participants affected / at risk	**7/140 (5.00%)**	**9/137 (6.57%)**	**11/147 (7.48%)**	**7/142 (4.93%)**
# events	**12**	**14**	**35**	**15**

1 Term from vocabulary, MedDRA 12.1

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

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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:** Principal investigator (PI) agrees not to publish or publicly present any interim results of the study without prior written consent of the sponsor. The PI further agrees to provide to the sponsor, 30 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, PI agrees to meet with the sponsor, prior to submission for publication, to discuss and resolve any such issues or disagreement.

Results Point of Contact:

Name/Title: Senior Vice President, Global Clinical Development
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Publications of Results:

Maspero J, Backer V, Yao R, Staudinger H, Teper A. Effects of mometasone, fluticasone, and montelukast on bone mineral density in adults with asthma. J Allergy Clin Immunol Pract. 2013 Nov-Dec;1(6):649-55.e1. doi: 10.1016/j.jaip.2013.07.011. Epub 2013 Oct 8.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00394355 History of Changes
Other Study ID Numbers:	P03418 Doc ID: 3387777; EUDRACT No: 2004-002930-21;
Study First Received:	October 31, 2006
Results First Received:	October 22, 2010
Last Updated:	June 23, 2015
Health Authority:	Argentina: Administracion Nacional de Medicamentos, Alimentos y Tecnologia Medica

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