Montelukast Asthmatic Smoker Study (0476-332)(COMPLETED)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00284856

First received: January 31, 2006
Last updated: March 27, 2015
Last verified: March 2015
History of Changes

Purpose

This is a multicenter study to evaluate the efficacy and safety of MK0476 versus placebo in participants with chronic asthma who actively smoke cigarettes.

Condition	Intervention	Phase
Asthma	Drug: montelukast sodium Drug: Comparator: Placebo Drug: Comparator: fluticasone	Phase 3

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

Official Title: A Multicenter, Randomized, Double-Blind, Parallel-Group 6-Month Study to Evaluate the Efficacy and Safety of Oral Montelukast Sodium, Fluticasone Propionate and Placebo in Patients With Chronic Asthma Who Smoke Cigarettes

Resource links provided by NLM:

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

U.S. FDA Resources

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

Primary Outcome Measures:

- Percentage of Asthma-control Days Over the 6-month Treatment Period [Time Frame: 6 months] [Designated as safety issue: No]

An asthma-control day, computed from daily diaries, was any day with no unscheduled visit for asthma care, no use of > than 2 puffs of β-agonist, no use of other asthma rescue medication, and no nocturnal awakening. The percentage of asthma-control days was the number of days with asthma-control divided by the total number of days with non-missing values for this endpoint. The patient diary had questions concerning daytime and nighttime symptoms, morning (AM) and evening (PM) peak expiratory flow rate (PEFR), β-agonist use, asthma attacks and smoking activity.

Secondary Outcome Measures:

- Change From Baseline in Mean Daytime Symptom Score Over a 6-month Treatment Period [Time Frame: Baseline and 6 months] [Designated as safety issue: No]

  4 daytime symptoms were evaluated daily on a 7-point scale from 0 (best)- 6 (worst). The on-treatment daytime symptom score was computed by averaging over Period II the mean of the 4 daily symptom scores recorded daily in the diary while the baseline daytime symptom score was obtained by averaging the mean of the 4 daily symptom scores across the daily diary entries of the Baseline period (Period I). The change from baseline in mean daytime symptom score is computed as the difference between the mean on-treatment daytime symptom score & the mean baseline daytime symptom score.

- Change From Baseline in Average Morning (AM) PEFR (Peak Expiratory Flow Rate) Over a 6-month Treatment Period [Time Frame: Baseline and 6 months] [Designated as safety issue: No]

  PEFR measurements were performed daily, in the morning before using any medication. The on-treatment AM PEFR was computed by averaging over Period II (treatment period) the AM PEFR recorded daily in the diary, while the baseline AM PEFR was obtained by averaging the AM PEFR across the daily diary entries of the Baseline Period or Period I (placebo run-in period). The change from baseline in average AM PEFR is computed as the difference between mean on-treatment AM PEFR and mean baseline AM PEFR.

Enrollment:	1640
Study Start Date:	May 2006
Study Completion Date:	April 2010
Primary Completion Date:	April 2010 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: 1 Arm 1: Montelukast	Drug: montelukast sodium montelukast 10 mg tablet once daily, 6 month treatment period Drug: Comparator: Placebo fluticasone propionate 250 mcg Placebo (Pbo) twice daily, 6 month treatment period
Active Comparator: 2 Arm 2: Fluticasone	Drug: Comparator: fluticasone fluticasone propionate 250 mcg twice daily, 6 month treatment period Drug: Comparator: Placebo montelukast 10 mg Pbo tablet once daily, 6 month treatment period
Placebo Comparator: 3 Arm 3: Placebo	Drug: Comparator: Placebo fluticasone propionate 250 mcg Placebo (Pbo) twice daily, 6 month treatment period Drug: Comparator: Placebo montelukast 10 mg Pbo tablet once daily, 6 month treatment period

Eligibility

Ages Eligible for Study:	18 Years to 55 Years
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Participants with chronic asthma who actively smoke at least 0.5 to no more than 2 packs of cigarettes a day

Exclusion Criteria:

Participant cannot have a diagnosis of Chronic Obstructive Pulmonary Disease (COPD) or emphysema.

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.

Please refer to this study by its ClinicalTrials.gov identifier: NCT00284856

Sponsors and Collaborators

Merck Sharp & Dohme Corp.

Investigators

Study Director: Medical Monitor Merck Sharp & Dohme Corp.

More Information

Additional Information:

MedWatch - FDA maintained medical product safety Information EXIT

Merck: Patient & Caregiver U.S. Product Web Site EXIT

Publications:

Price D, Popov TA, Bjermer L, Lu S, Petrovic R, Vandormael K, Mehta A, Strus JD, Polos PG, Philip G. Effect of montelukast for treatment of asthma in cigarette smokers. J Allergy Clin Immunol. 2013 Mar;131(3):763-71. doi: 10.1016/j.jaci.2012.12.673. Epub 2013 Feb 4.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00284856 History of Changes
Other Study ID Numbers:	0476-332 2005_108
Study First Received:	January 31, 2006
Results First Received:	April 6, 2011
Last Updated:	March 27, 2015
Health Authority:	Peru: General Directorate of Pharmaceuticals, Devices, and Drugs

Additional relevant MeSH terms:

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

ClinicalTrials.gov processed this record on April 13, 2016

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ClinicalTrials.gov Identifier:
NCT00284856

First received: January 31, 2006
Last updated: March 27, 2015
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History of Changes

Results First Received: April 6, 2011

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Treatment
Condition:	Asthma
Interventions:	Drug: montelukast sodium Drug: Comparator: Placebo Drug: Comparator: fluticasone

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
Of the 1640 participants enrolled in the study, 621 participants were excluded during screening and not randomized. The remaining 1019 participants were randomized.

Reporting Groups

	Description
Montelukast	Montelukast 10 mg tablet once daily at bedtime and Fluticasone propionate matching placebo 250 mcg twice daily for 6 months
Fluticasone	Fluticasone propionate 250 mcg twice daily and Montelukast matching placebo 10 mg tablet once daily at bedtime for 6 months
Placebo	Montelukast matching placebo 10 mg tablet once daily at bedtime and Fluticasone propionate matching placebo 250 mcg twice daily for 6 months

Participant Flow: Overall Study

	Montelukast	Fluticasone	Placebo
STARTED	347	336	336
COMPLETED	296	286	276
NOT COMPLETED	51	50	60
Adverse Event	3	3	3
Lack of Efficacy	2	1	8
Lost to Follow-up	25	21	22
Protocol Violation	5	4	5
Withdrawal by Subject	12	16	18
Unspecified	4	5	4

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
Montelukast	Montelukast 10 mg tablet once daily at bedtime and Fluticasone propionate matching placebo 250 mcg twice daily for 6 months
Fluticasone	Fluticasone propionate 250 mcg twice daily and Montelukast matching placebo 10 mg tablet once daily at bedtime for 6 months
Placebo	Montelukast matching placebo 10 mg tablet once daily at bedtime and Fluticasone propionate matching placebo 250 mcg twice daily for 6 months
Total	Total of all reporting groups

Baseline Measures

	Montelukast	Fluticasone	Placebo	Total
Number of Participants [units: participants]	347	336	336	1019
Age			37.9 (9.9)	38.0 (10.3)

[units: years] Mean (Standard Deviation)	37.7 (10.4)	38.4 (10.7)		
Gender [units: participants]				
Female	163	147	166	476
Male	184	189	170	543

Outcome Measures

Hide All Outcome Measures

1. Primary: Percentage of Asthma-control Days Over the 6-month Treatment Period [Time Frame: 6 months]

Measure Type	Primary
Measure Title	Percentage of Asthma-control Days Over the 6-month Treatment Period
Measure Description	An asthma-control day, computed from daily diaries, was any day with no unscheduled visit for asthma care, no use of > than 2 puffs of β-agonist, no use of other asthma rescue medication, and no nocturnal awakening. The percentage of asthma-control days was the number of days with asthma-control divided by the total number of days with non-missing values for this endpoint. The patient diary had questions concerning daytime and nighttime symptoms, morning (AM) and evening (PM) peak expiratory flow rate (PEFR), β-agonist use, asthma attacks and smoking activity.
Time Frame	6 months
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.
Efficacy analysis was based on the full analysis set (FAS) population which included all participants who had at least 7 days of on-treatment data for the specific endpoint. Thirty three patients were excluded from the FAS (13 on montelukast, 7 on fluticasone and 13 on placebo). One participant in the placebo group did not take study medication.

Reporting Groups

	Description
Montelukast	Montelukast 10 mg tablet once daily at bedtime and Fluticasone propionate matching placebo 250 mcg twice daily for 6 months
Fluticasone	Fluticasone propionate 250 mcg twice daily and Montelukast matching placebo 10 mg tablet once daily at bedtime for 6 months
Placebo	Montelukast matching placebo 10 mg tablet once daily at bedtime and Fluticasone propionate matching placebo 250 mcg twice daily for 6 months

Measured Values

	Montelukast	Fluticasone	Placebo
Number of Participants Analyzed [units: participants]	334	329	323
Percentage of Asthma-control Days Over the 6-month Treatment Period [units: Percentage of days] Mean (Standard Deviation)	50.70 (38.19)	53.30 (39.06)	43.84 (38.08)

Statistical Analysis 1 for Percentage of Asthma-control Days Over the 6-month Treatment Period

Groups [1]	Montelukast vs. Placebo
Least Squares Mean Difference [2]	5.92
95% Confidence Interval	0.28 to 11.56

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant estimation information:
	Estimated Value is difference in least squares mean (montelukast - placebo)

Statistical Analysis 2 for Percentage of Asthma-control Days Over the 6-month Treatment Period

Groups [1]	Fluticasone vs. Placebo
Least Squares Mean Difference [2]	10.14
95% Confidence Interval	4.50 to 15.78

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant estimation information:
	Estimated value is difference in least squares mean (fluticasone - placebo)

Statistical Analysis 3 for Percentage of Asthma-control Days Over the 6-month Treatment Period

Groups [1]	Montelukast vs. Fluticasone
Least Squares Mean Difference [2]	-4.22
95% Confidence Interval	-9.83 to 1.38

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant estimation information:
	Estimated value is difference in least squares mean (montelukast - fluticasone)

2. Secondary: Change From Baseline in Mean Daytime Symptom Score Over a 6-month Treatment Period [Time Frame: Baseline and 6 months]

Measure Type	Secondary
Measure Title	Change From Baseline in Mean Daytime Symptom Score Over a 6-month Treatment Period
Measure Description	4 daytime symptoms were evaluated daily on a 7-point scale from 0 (best)- 6 (worst). The on-treatment daytime symptom score was computed by averaging over Period II the mean of the 4 daily symptom scores recorded daily in the diary while the baseline daytime symptom score was obtained by averaging the mean of the 4 daily symptom scores across the daily diary entries of the Baseline period (Period I). The change from baseline in mean daytime symptom score is computed as the difference between the mean on-treatment daytime symptom score & the mean baseline daytime symptom score.
Time Frame	Baseline and 6 months

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.
Efficacy analysis was based on the full analysis set (FAS) population which included all participants who received at least one dose of the randomized double-blind study medication and who had at least 7 days of on-treatment data for the specific endpoint.

Reporting Groups

	Description
Montelukast	Montelukast 10 mg tablet once daily at bedtime and Fluticasone propionate matching placebo 250 mcg twice daily for 6 months
Fluticasone	Fluticasone propionate 250 mcg twice daily and Montelukast matching placebo 10 mg tablet once daily at bedtime for 6 months
Placebo	Montelukast matching placebo 10 mg tablet once daily at bedtime and Fluticasone propionate matching placebo 250 mcg twice daily for 6 months

Measured Values

	Montelukast	**Fluticasone**	**Placebo**
Number of Participants Analyzed [units: participants]	**335**	**329**	**322**
Change From Baseline in Mean Daytime Symptom Score Over a 6-month Treatment Period [units: Score on a scale] Mean (Standard Deviation)			
Baseline	**1.82 (1.03)**	**1.78 (0.97)**	**1.90 (0.94)**
Average Change from Baseline During Period II	**-0.41 (0.70)**	**-0.44 (0.68)**	**-0.27 (0.72)**

Statistical Analysis 1 for Change From Baseline in Mean Daytime Symptom Score Over a 6-month Treatment Period

Groups [1]	Montelukast vs. Placebo
Least Squares Mean Difference [2]	-0.15
95% Confidence Interval	-0.25 to -0.05

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant estimation information:
	Estimated value is difference in least squares mean (montelukast - placebo)

Statistical Analysis 2 for Change From Baseline in Mean Daytime Symptom Score Over a 6-month Treatment Period

Groups [1]	Fluticasone vs. Placebo
Least Squares Mean Difference [2]	-0.20
95% Confidence Interval	-0.30 to -0.10

[1]	Additional details about the analysis, such as null hypothesis and power calculation:

	No text entered.
[2]	Other relevant estimation information:
	Estimated value is difference in least squares mean (fluticasone - placebo)

Statistical Analysis 3 for Change From Baseline in Mean Daytime Symptom Score Over a 6-month Treatment Period

Groups [1]	Montelukast vs. Fluticasone
Least Squares Mean Difference [2]	0.05
95% Confidence Interval	-0.05 to 0.15

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant estimation information:
	Estimated value is difference in least squares mean (montelukast - fluticasone)

3. Secondary: Change From Baseline in Average Morning (AM) PEFR (Peak Expiratory Flow Rate) Over a 6-month Treatment Period [Time Frame: Baseline and 6 months]

Measure Type	Secondary
Measure Title	Change From Baseline in Average Morning (AM) PEFR (Peak Expiratory Flow Rate) Over a 6-month Treatment Period
Measure Description	PEFR measurements were performed daily, in the morning before using any medication. The on-treatment AM PEFR was computed by averaging over Period II (treatment period) the AM PEFR recorded daily in the diary, while the baseline AM PEFR was obtained by averaging the AM PEFR across the daily diary entries of the Baseline Period or Period I (placebo run-in period). The change from baseline in average AM PEFR is computed as the difference between mean on-treatment AM PEFR and mean baseline AM PEFR.
Time Frame	Baseline and 6 months
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.
Efficacy analysis was based on the full analysis set (FAS) population which included all participants who received at least one dose of the randomized double-blind study medication and who had at least 7 days of on-treatment data for the specific endpoint.

Reporting Groups

	Description
Montelukast	Montelukast 10 mg tablet once daily at bedtime and Fluticasone propionate matching placebo 250 mcg twice daily for 6 months
Fluticasone	Fluticasone propionate 250 mcg twice daily and Montelukast matching placebo 10 mg tablet once daily at bedtime for 6 months
Placebo	Montelukast matching placebo 10 mg tablet once daily at bedtime and Fluticasone propionate matching placebo 250 mcg twice daily for 6 months

Measured Values

	Montelukast	**Fluticasone**	**Placebo**

Number of Participants Analyzed [units: participants]	**334**	**329**	**324**
Change From Baseline in Average Morning (AM) PEFR (Peak Expiratory Flow Rate) Over a 6-month Treatment Period [units: Liters/minute] Mean (Standard Deviation)			
Baseline	**363.75 (112.40)**	**354.28 (101.64)**	**347.98 (99.21)**
Average Change from Baseline During Period II	**12.84 (40.22)**	**19.31 (44.85)**	**8.27 (40.70)**

Statistical Analysis 1 for Change From Baseline in Average Morning (AM) PEFR (Peak Expiratory Flow Rate) Over a 6-month Treatment Period

Groups [1]	Montelukast vs. Placebo
Least Squares Mean Difference [2]	5.09
95% Confidence Interval	-1.27 to 11.45

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant estimation information:
	Estimated value is difference in least squares mean (montelukast - placebo)

Statistical Analysis 2 for Change From Baseline in Average Morning (AM) PEFR (Peak Expiratory Flow Rate) Over a 6-month Treatment Period

Groups [1]	Fluticasone vs. Placebo
Least Squares Mean Difference [2]	11.21
95% Confidence Interval	4.85 to 17.58

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant estimation information:
	Estimated value is difference in least squares mean (fluticasone - placebo)

Statistical Analysis 3 for Change From Baseline in Average Morning (AM) PEFR (Peak Expiratory Flow Rate) Over a 6-month Treatment Period

Groups [1]	Montelukast vs. Fluticasone
Least Squares Mean Difference [2]	-6.13
95% Confidence Interval	-12.46 to 0.20

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant estimation information:
	Estimated value is difference in least squares mean (montelukast - fluticasone)

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	The population for safety analyses was the All Patients as Treated (APaT) set. The set included all randomized participants who took at least one dose of the double-blind study medication. One participant in the placebo group was randomized but did not take treatment. Therefore, participant was not included in the safety analyses.

Reporting Groups

	Description
Montelukast	Montelukast 10 mg tablet once daily at bedtime and Fluticasone propionate matching placebo 250 mcg twice daily for 6 months
Fluticasone	Fluticasone propionate 250 mcg twice daily and Montelukast matching placebo 10 mg tablet once daily at bedtime for 6 months
Placebo	Montelukast matching placebo 10 mg tablet once daily at bedtime and Fluticasone propionate matching placebo 250 mcg twice daily for 6 months

Serious Adverse Events

	Montelukast	Fluticasone	Placebo
Total, serious adverse events			
# participants affected / at risk	**9/347 (2.59%)**	**10/336 (2.98%)**	**11/335 (3.28%)**
Cardiac disorders			
Cardiac arrest † 1			
# participants affected / at risk	**0/347 (0.00%)**	**1/336 (0.30%)**	**0/335 (0.00%)**
# events	**0**	**1**	**0**
Congenital, familial and genetic disorders			
Dermoid cyst † 1			
# participants affected / at risk	**1/347 (0.29%)**	**0/336 (0.00%)**	**0/335 (0.00%)**
# events	**1**	**0**	**0**
Gastrointestinal disorders			
Haemorrhoids † 1			
# participants affected / at risk	**0/347 (0.00%)**	**1/336 (0.30%)**	**0/335 (0.00%)**
# events	**0**	**1**	**0**
Hiatus hernia † 1			
# participants affected / at risk	**0/347 (0.00%)**	**0/336 (0.00%)**	**1/335 (0.30%)**
# events	**0**	**0**	**1**
Hepatobiliary disorders			
Autoimmune hepatitis † 1			
# participants affected / at risk	**0/347 (0.00%)**	**1/336 (0.30%)**	**0/335 (0.00%)**
# events	**0**	**1**	**0**
Cholecystitis † 1			
# participants affected / at risk	**1/347 (0.29%)**	**0/336 (0.00%)**	**0/335 (0.00%)**
# events	**1**	**0**	**0**

Infections and infestations			
Appendicitis † 1			
# participants affected / at risk	**0/347 (0.00%)**	**0/336 (0.00%)**	**1/335 (0.30%)**
# events	**0**	**0**	**1**
Endometritis † 1			
# participants affected / at risk	**1/347 (0.29%)**	**0/336 (0.00%)**	**0/335 (0.00%)**
# events	**1**	**0**	**0**
Respiratory tract infection † 1			
# participants affected / at risk	**0/347 (0.00%)**	**0/336 (0.00%)**	**1/335 (0.30%)**
# events	**0**	**0**	**1**
Salpingo-oophoritis † 1			
# participants affected / at risk	**1/347 (0.29%)**	**0/336 (0.00%)**	**0/335 (0.00%)**
# events	**1**	**0**	**0**
Upper respiratory tract infection † 1			
# participants affected / at risk	**1/347 (0.29%)**	**0/336 (0.00%)**	**0/335 (0.00%)**
# events	**1**	**0**	**0**
Urinary tract infection † 1			
# participants affected / at risk	**1/347 (0.29%)**	**0/336 (0.00%)**	**0/335 (0.00%)**
# events	**1**	**0**	**0**
Injury, poisoning and procedural complications			
Accidental overdose † 1			
# participants affected / at risk	**0/347 (0.00%)**	**2/336 (0.60%)**	**6/335 (1.79%)**
# events	**0**	**2**	**7**
Brain herniation † 1			
# participants affected / at risk	**0/347 (0.00%)**	**1/336 (0.30%)**	**0/335 (0.00%)**
# events	**0**	**1**	**0**
Intentional overdose † 1			
# participants affected / at risk	**0/347 (0.00%)**	**0/336 (0.00%)**	**1/335 (0.30%)**
# events	**0**	**0**	**1**
Post procedural haemorrhage † 1			
# participants affected / at risk	**0/347 (0.00%)**	**1/336 (0.30%)**	**0/335 (0.00%)**
# events	**0**	**1**	**0**
Rib fracture † 1			
# participants affected / at risk	**0/347 (0.00%)**	**0/336 (0.00%)**	**1/335 (0.30%)**
# events	**0**	**0**	**1**
Musculoskeletal and connective tissue disorders			
Bursitis † 1			
# participants affected / at risk	**1/347 (0.29%)**	**0/336 (0.00%)**	**0/335 (0.00%)**
# events	**1**	**0**	**0**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Gastric cancer † 1			
# participants affected / at risk	**0/347 (0.00%)**	**1/336 (0.30%)**	**0/335 (0.00%)**
# events	**0**	**1**	**0**
Nervous system disorders			

Cerebral infarction † 1			
# participants affected / at risk	**1/347 (0.29%)**	**0/336 (0.00%)**	**0/335 (0.00%)**
# events	**1**	**0**	**0**
Cerebrovascular accident † 1			
# participants affected / at risk	**1/347 (0.29%)**	**0/336 (0.00%)**	**0/335 (0.00%)**
# events	**1**	**0**	**0**
Facial palsy † 1			
# participants affected / at risk	**1/347 (0.29%)**	**0/336 (0.00%)**	**0/335 (0.00%)**
# events	**1**	**0**	**0**
Respiratory, thoracic and mediastinal disorders			
Asthma † 1			
# participants affected / at risk	**1/347 (0.29%)**	**2/336 (0.60%)**	**2/335 (0.60%)**
# events	**1**	**5**	**3**
Asthmatic crisis † 1			
# participants affected / at risk	**0/347 (0.00%)**	**1/336 (0.30%)**	**0/335 (0.00%)**
# events	**0**	**1**	**0**
Surgical and medical procedures			
Abortion induced † 1			
# participants affected / at risk	**0/347 (0.00%)**	**1/336 (0.30%)**	**0/335 (0.00%)**
# events	**0**	**1**	**0**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 12.1

Other Adverse Events

Hide Other Adverse Events

Time Frame	No text entered.
Additional Description	The population for safety analyses was the All Patients as Treated (APaT) set. The set included all randomized participants who took at least one dose of the double-blind study medication. One participant in the placebo group was randomized but did not take treatment. Therefore, participant was not included in the safety analyses.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Montelukast	Montelukast 10 mg tablet once daily at bedtime and Fluticasone propionate matching placebo 250 mcg twice daily for 6 months
Fluticasone	Fluticasone propionate 250 mcg twice daily and Montelukast matching placebo 10 mg tablet once daily at bedtime for 6 months
Placebo	Montelukast matching placebo 10 mg tablet once daily at bedtime and Fluticasone propionate matching placebo 250 mcg twice daily for 6 months

Other Adverse Events

	Montelukast	Fluticasone	Placebo
Total, other (not including serious) adverse events			
# participants affected / at risk	**65/347 (18.73%)**	**57/336 (16.96%)**	**72/335 (21.49%)**
Infections and infestations			
Nasopharyngitis † 1			
# participants affected / at risk	**23/347 (6.63%)**	**27/336 (8.04%)**	**22/335 (6.57%)**
# events	**30**	**34**	**26**
Respiratory, thoracic and mediastinal disorders			
Asthma † 1			
# participants affected / at risk	**45/347 (12.97%)**	**34/336 (10.12%)**	**57/335 (17.01%)**
# events	**71**	**50**	**95**

† Events were collected by systematic assessment
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

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 SPONSOR must have the opportunity to review all proposed abstracts,
manuscripts, or presentations regarding this study 60 days prior to submission for publication/presentation. Any information identified by the SPONSOR as
confidential must be deleted prior to submission. SPONSOR review can be expedited to meet publication guidelines.

Results Point of Contact:

Name/Title: Senior Vice President, Global Clinical Development
Organization: Merck Sharp & Dohme Corp
phone: 1-800-672-6372
e-mail: ClinicalTrialsDisclosure@merck.com

Publications of Results:

Price D, Popov TA, Bjermer L, Lu S, Petrovic R, Vandormael K, Mehta A, Strus JD, Polos PG, Philip G. Effect of montelukast for treatment of asthma in cigarette smokers. J Allergy Clin Immunol. 2013 Mar;131(3):763-71. doi: 10.1016/j.jaci.2012.12.673. Epub 2013 Feb 4.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00284856 History of Changes
Other Study ID Numbers:	0476-332 2005_108
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Last Updated:	March 27, 2015
Health Authority:	Peru: General Directorate of Pharmaceuticals, Devices, and Drugs

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