Mometasone Furoate on Sleep Disturbances in Subjects With Seasonal Allergic Rhinitis (Study P04608) (COMPLETED)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

Collaborator:
Integrated Therapeutics Group

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

ClinicalTrials.gov Identifier:
NCT00358527

First received: July 31, 2006
Last updated: July 21, 2015
Last verified: July 2015
History of Changes

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Purpose

This study will hope to show that by relieving the participant's nasal symptoms of seasonal allergies using mometasone furoate nasal spray, the participant will obtain a better quality of night-time sleep, which in turn, causes less daytime sleepiness so that he/she can function productively during the day.

Condition	Intervention	Phase
Seasonal Allergic Rhinitis	Drug: Mometasone Furoate Nasal Spray (MFNS) Other: Placebo	Phase 4

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

Official Title: A Double-Blind, Placebo-Controlled, Randomized, Parallel-Group Multicenter Study of Mometasone Furoate Nasal Spray on Sleep Disturbances and Daytime Somnolence in Subjects With Symptomatic Seasonal Allergic Rhinitis

Resource links provided by NLM:

MedlinePlus related topics: Hay Fever

Drug Information available for: Mometasone furoate Mometasone furoate monohydrate

U.S. FDA Resources

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

Primary Outcome Measures:

- Mean Change of the AM-PRIOR-reflective (Participant's Status Over the Previous 12 Hours) Total Nasal Symptoms Severity Score (TNSS) Averaged Over the Last 7 Days of Treatment From the Baseline Score. [Time Frame: Average of the last 7 days of treatment] [Designated as safety issue: No]

  The TNSS score included the sum of nasal congestion/stuffiness, rhinorrhea/nasal discharge, sneezing, and nasal itching, each scored on a scale of 0 = absent, 1 = mild, 2 = moderate, 3 = severe. The TNSS score could range from 0 to 12. NOTE: Least square means and standard errors were obtained from an ANCOVA model with the treatment effect and the variable specific Baseline as a covariate.

- Mean Change From Baseline (Day 1/Visit 3) in the Sleep Problems Index II (SLP9) Score From the Medical Outcome Study Sleep Scale (MOS-SS) at the Day 29 Visit. [Time Frame: 29 days] [Designated as safety issue: No]

  Following Visit 2 (Screening), at Baseline, Day 15, and Day 29 visits, participants needed to complete the MOS-SS questionnaire with scores from 1 = all of the time to 6 = none of the time, according to their frequency of occurrence during the previous week. The analysis endpoint MOS-SS Sleep Problems Index II (SLP9) score was derived from MOS-SS questionnaire and scaled from 0 = none of the time to 100 = all of the time. NOTE: Least squares means and standard errors were obtained from an ANCOVA model with the treatment effect and the variable specific Baseline as a covariate.

Enrollment:	401
Study Start Date:	May 2006
Study Completion Date:	November 2006
Primary Completion Date:	October 2006 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Mometasone Furoate Nasal Spray Mometasone Furoate Nasal Spray 200 mcg, once daily.	Drug: Mometasone Furoate Nasal Spray (MFNS) MFNS 50 mcg/spray: self-administered, two sprays per nostril (ie, 200 mcg QD), once daily (each morning), for 28 days. Other Name: MFNS
Placebo Comparator: Matching placebo nasal spray	Other: Placebo Matching placebo nasal spray: 2 sprays per nostril once daily for 28 days

Eligibility

Ages Eligible for Study:	18 Years and older
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Must be >=18 years of age and older, of either sex, and of any race.
- Clinically symptomatic at Screening (Day -7 to -4)and at Baseline (Day 1)
- At Screening Visit, must have complaints of sleep disturbance while symptomatic with seasonal allergic rhinitis (SAR) and must have a score of 30 or greater for the Sleep Disturbance Sleep Scale (items 1,3,7 and 8)
- At the Baseline Visit, must have complaints of sleep disturbance and daytime somnolence while symptomatic with SAR and with a score of 30 or greater for the Sleep Problems Index II (SLP9) and 30 or greater for the Daytime Somnolence Sleep Scale (items 6, 9, and 11)
- Must have a 2-year or longer history of SAR occurring during the same season as the current study.
- Must have skin tests positive for outdoor allergens common in subjects with SAR prevalent during the time of this study, such as, trees, grasses, weeds, ragweed, and molds. The skin tests should be performed at Screening if not done within 12 months prior to the Screening Visit
- Must be free of clinically significant disease that would interfere with study evaluations
- Women of childbearing potential need to use a medically accepted method of birth control prior to Screening and during the study, or provide documentation of surgical sterilization. Women who are not sexually active at enrollment must consent to the use of a medically accepted method of birth control if/when they become sexually active during study participation.

- Female subjects of childbearing potential must have a negative urine pregnancy test at the time of enrollment at the Baseline Visit.

Exclusion Criteria:

- Women who are pregnant, intend to become pregnant during the study, or are nursing
- Evidence of nasal polyps, deviated septum, or other intranasal anatomical obstruction(s) that would interfere with nasal airflow
- Acute or chronic sinusitis being treated with antibiotics and/or topical or oral nasal decongestants
- Acute respiratory infection within 2 weeks of the Screening Visit
- Diagnosis of clinically relevant sleep problems unassociated with allergies
- Complaints (within 12 months of the Screening Visit to their health-care provider) of difficulty sleeping or daytime sleepiness while not experiencing SAR symptoms, and continue with these complaints
- Snoring associated with an enlarged uvula or other upper airway pathology
- Had episodes of snoring associated with gasping or choking
- Awakened suddenly, on more than 1 occasion during the month preceding the Screening Visit, with a gasping or choking feeling
- Requires the use of oral appliances at night for bruxism (teeth gnashing) or temporomandibular joint problems
- Diagnosis of asthma with daytime and nighttime asthma symptoms not controlled by short-acting beta-2 adrenoceptor agonists
- Dependence on nasal, oral or ocular decongestants, nasal topical antihistamines, or nasal steroids.
- Currently undergoing a progressive course of immunotherapy (hyposensitization). Subjects on a regular maintenance schedule prior to the Screening Visit and who wish to remain on this schedule during the study are eligible for study inclusion; however, they may not receive hyposensitization treatment within 24 hours prior to any study visit
- Smokers or ex-smokers who have smoked within the previous 6 months
- Concomitant medical problem that may interfere with participation in the study, eg, repeated migraine episodes, uncontrolled convulsive disorders.
- Any of the following clinical conditions: Active or quiescent tuberculosis infection of the respiratory tract, untreated fungal, bacterial, systemic viral infections or ocular herpes simplex.
- Subjects participating in any other clinical study(ies).
- Subjects allergic to or with a sensitivity to the study drug or its excipients.
- Subjects who are night-shift workers or do not have a standard "asleep at night/awake during the day" cycle

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

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00358527 History of Changes
Other Study ID Numbers:	P04608
Study First Received:	July 31, 2006
Results First Received:	February 18, 2010
Last Updated:	July 21, 2015
Health Authority:	Belgium: Federal Agency for Medicines and Health Products, FAMHP Canada: Health Canada France: Afssaps - Agence française de sécurité sanitaire des produits de santé (Saint-Denis) Germany: Federal Institute for Drugs and Medical Devices Italy: The Italian Medicines Agency Netherlands: The Central Committee on Research Involving Human Subjects (CCMO) Russia: Pharmacological Committee, Ministry of Health Spain: Spanish Agency of Medicines United Kingdom: Medicines and Healthcare Products Regulatory Agency

Additional relevant MeSH terms:

Dyssomnias	Nose Diseases
Parasomnias	Otorhinolaryngologic Diseases

Rhinitis
Rhinitis, Allergic, Seasonal
Sleep Disorders
Hypersensitivity
Hypersensitivity, Immediate
Immune System Diseases
Mental Disorders
Nervous System Diseases
Neurologic Manifestations
Respiratory Hypersensitivity
Respiratory Tract Diseases
Respiratory Tract Infections
Signs and Symptoms
Mometasone furoate
Anti-Allergic Agents
Anti-Inflammatory Agents
Pharmacologic Actions
Therapeutic Uses

ClinicalTrials.gov processed this record on May 08, 2016

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Results First Received: February 18, 2010

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Treatment
Condition:	Seasonal Allergic Rhinitis
Interventions:	Drug: Mometasone Furoate Nasal Spray (MFNS) Other: 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
Mometasone Furoate Nasal Spray	Mometasone Furoate Nasal Spray; 50 mcg/spray: self-administered, two sprays per nostril (ie, 200 mcg), once daily (each morning), for 28 days.
Placebo Nasal Spray.	Matching placebo nasal spray. Two sprays per nostril once daily, for 28 days.

Participant Flow: Overall Study

	Mometasone Furoate Nasal Spray	Placebo Nasal Spray.
STARTED	**267**	**134**
COMPLETED	**254**	**131**
NOT COMPLETED	**13**	**3**
Adverse Event	**4**	**0**
Withdrawal by Subject	**1**	**1**
Non-compliance with protocol	**6**	**1**
Administrative	**2**	**1**

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
Mometasone Furoate Nasal Spray	Mometasone Furoate Nasal Spray; 50 mcg/spray: self-administered, two sprays per nostril (ie, 200 mcg), once daily (each morning), for 28 days.
Placebo Nasal Spray.	Matching placebo nasal spray. Two sprays per nostril once daily, for 28 days.
Total	Total of all reporting groups

Baseline Measures

	Mometasone Furoate Nasal Spray	Placebo Nasal Spray.	Total
Number of Participants [units: participants]	**267**	**134**	**401**
Age [units: participants]			
<=18 years	**0**	**0**	**0**
Between 18 and 65 years	**259**	**132**	**391**
>=65 years	**8**	**2**	**10**

Age [units: years] Mean (Standard Deviation)	**36.1 (12.8)**	**35.1 (11.8)**	**35.7 (12.5)**
Gender [units: participants]			
Female	**170**	**85**	**255**
Male	**97**	**49**	**146**

Outcome Measures

Hide All Outcome Measures

1. Primary: Mean Change of the AM-PRIOR-reflective (Participant's Status Over the Previous 12 Hours) Total Nasal Symptoms Severity Score (TNSS) Averaged Over the Last 7 Days of Treatment From the Baseline Score. [Time Frame: Average of the last 7 days of treatment]

Measure Type	Primary
Measure Title	Mean Change of the AM-PRIOR-reflective (Participant's Status Over the Previous 12 Hours) Total Nasal Symptoms Severity Score (TNSS) Averaged Over the Last 7 Days of Treatment From the Baseline Score.
Measure Description	The TNSS score included the sum of nasal congestion/stuffiness, rhinorrhea/nasal discharge, sneezing, and nasal itching, each scored on a scale of 0 = absent, 1 = mild, 2 = moderate, 3 = severe. The TNSS score could range from 0 to 12. NOTE: Least square means and standard errors were obtained from an ANCOVA model with the treatment effect and the variable specific Baseline as a covariate.
Time Frame	Average of the last 7 days 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.
Modified Intent-to-Treat (MITT) Population: all randomized subjects with any post-baseline data and without concomitant medications that could significantly bias the co-primary endpoints.

Reporting Groups

	Description
Mometasone Furoate Nasal Spray	Mometasone Furoate Nasal Spray; 50 mcg/spray: self-administered, two sprays per nostril (ie, 200 mcg), once daily (each morning), for 28 days.
Placebo Nasal Spray.	Matching placebo nasal spray. Two sprays per nostril once daily, for 28 days.

Measured Values

	Mometasone Furoate Nasal Spray	**Placebo Nasal Spray.**
Number of Participants Analyzed [units: participants]	**248**	**131**
Mean Change of the AM-PRIOR-reflective (Participant's Status Over the Previous 12 Hours) Total Nasal Symptoms Severity Score (TNSS) Averaged Over the Last 7 Days of Treatment From the Baseline Score. [units: Units on a scale]		

Least Squares Mean (Standard Error)		
Change from Baseline in TNSS score	**-3.77 (0.19)**	**-3.07 (0.26)**
Baseline TNSS score	**9.10 (0.10)**	**9.12 (0.14)**

No statistical analysis provided for Mean Change of the AM-PRIOR-reflective (Participant's Status Over the Previous 12 Hours) Total Nasal Symptoms Severity Score (TNSS) Averaged Over the Last 7 Days of Treatment From the Baseline Score.

2. Primary: Mean Change From Baseline (Day 1/Visit 3) in the Sleep Problems Index II (SLP9) Score From the Medical Outcome Study Sleep Scale (MOS-SS) at the Day 29 Visit. [Time Frame: 29 days]

Measure Type	Primary
Measure Title	Mean Change From Baseline (Day 1/Visit 3) in the Sleep Problems Index II (SLP9) Score From the Medical Outcome Study Sleep Scale (MOS-SS) at the Day 29 Visit.
Measure Description	Following Visit 2 (Screening), at Baseline, Day 15, and Day 29 visits, participants needed to complete the MOS-SS questionnaire with scores from 1 = all of the time to 6 = none of the time, according to their frequency of occurrence during the previous week. The analysis endpoint MOS-SS Sleep Problems Index II (SLP9) score was derived from MOS-SS questionnaire and scaled from 0 = none of the time to 100 = all of the time. NOTE: Least squares means and standard errors were obtained from an ANCOVA model with the treatment effect and the variable specific Baseline as a covariate.
Time Frame	29 days
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.
Modified Intent-to-Treat (MITT) Population: all randomized subjects with any post-baseline data and without concomitant medications that could significantly bias the co-primary endpoints.

Reporting Groups

	Description
Mometasone Furoate Nasal Spray	Mometasone Furoate Nasal Spray; 50 mcg/spray: self-administered, two sprays per nostril (ie, 200 mcg), once daily (each morning), for 28 days.
Placebo Nasal Spray.	Matching placebo nasal spray. Two sprays per nostril once daily, for 28 days.

Measured Values

	Mometasone Furoate Nasal Spray	**Placebo Nasal Spray.**
Number of Participants Analyzed [units: participants]	**243**	**126**
Mean Change From Baseline (Day 1/Visit 3) in the Sleep Problems Index II (SLP9) Score From the Medical Outcome Study Sleep Scale (MOS-SS) at the Day 29 Visit. [units: Units on a scale] Least Squares Mean (Standard Error)		
Change from baseline in SLP9 score	**-26.1 (1.38)**	**-25.8 (1.90)**

Baseline SLP9 Score	**68.6 (0.86)**	**69.2 (1.20)**

No statistical analysis provided for Mean Change From Baseline (Day 1/Visit 3) in the Sleep Problems Index II (SLP9) Score From the Medical Outcome Study Sleep Scale (MOS-SS) at the Day 29 Visit.

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
Mometasone Furoate Nasal Spray	Mometasone Furoate Nasal Spray; 50 mcg/spray: self-administered, two sprays per nostril (ie, 200 mcg), once daily (each morning), for 28 days.
Placebo Nasal Spray.	Matching placebo nasal spray. Two sprays per nostril once daily, for 28 days.

Serious Adverse Events

	Mometasone Furoate Nasal Spray	Placebo Nasal Spray.
Total, serious adverse events		
# participants affected / at risk	**1/267 (0.37%)**	**0/134 (0.00%)**
Immune system disorders		
Food allergy † 1		
# participants affected / at risk	**1/267 (0.37%)**	**0/134 (0.00%)**
# events	**1**	**0**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA (9.1)

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
Mometasone Furoate Nasal Spray	Mometasone Furoate Nasal Spray; 50 mcg/spray: self-administered, two sprays per nostril (ie, 200 mcg), once daily (each morning), for 28 days.
Placebo Nasal Spray.	Matching placebo nasal spray. Two sprays per nostril once daily, for 28 days.

Other Adverse Events

	Mometasone Furoate Nasal Spray	Placebo Nasal Spray.
Total, other (not including serious) adverse events		
# participants affected / at risk	**10/267 (3.75%)**	**7/134 (5.22%)**
Nervous system disorders		
Headache † 1		
# participants affected / at risk	**10/267 (3.75%)**	**7/134 (5.22%)**
# events	**16**	**8**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA (9.1)

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 PI is not allowed to release any interim results of the Study without prior consent of the sponsor, and must provide 45 days written notice to the sponsor prior to public release to permit the sponsor's review. The PI can use the study results for his/her own teaching, research, and publication purposes only, not for commercial purposes, except as authorized by the sponsor. No publication shall contain any trade secret or proprietary/confidential information of the sponsor.

Results Point of Contact:

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

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Study First Received:	July 31, 2006
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Health Authority:	Belgium: Federal Agency for Medicines and Health Products, FAMHP Canada: Health Canada France: Afssaps - Agence française de sécurité sanitaire des produits de santé (Saint-Denis) Germany: Federal Institute for Drugs and Medical Devices Italy: The Italian Medicines Agency Netherlands: The Central Committee on Research Involving Human Subjects (CCMO) Russia: Pharmacological Committee, Ministry of Health Spain: Spanish Agency of Medicines United Kingdom: Medicines and Healthcare Products Regulatory Agency

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