An Exploratory Study of Nasonex in Patients With Moderate to Severe Persistent Allergic Rhinitis and Intermittent Asthma

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00599027

First received: January 10, 2008
Last updated: March 27, 2015
Last verified: March 2015
History of Changes

Purpose

The primary objective of this study is to explore the efficacy of Nasonex (mometasone furoate nasal spray) in comparison with placebo in improving the quality of life of subjects with moderate to severe persistent allergic rhinitis and intermittent asthma. A secondary objective is to evaluate the efficacy of Nasonex in relieving the subject's symptoms of allergic rhinitis and asthma.

Condition	Intervention	Phase
Allergic Rhinitis Asthma	Drug: Mometasone furoate nasal spray (MFNS) Drug: Placebo nasal spray	Phase 3

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

Official Title: An Exploratory Study of Mometasone Furoate Nasal Spray in Patients With Moderate-severe Persistent Allergic Rhinitis and Intermittent Asthma: Effects on the Quality of Life Evaluated With the Rhinasthma Questionnaire

Resource links provided by NLM:

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:

The Change of the Rhinasthma Global Summary Score From Baseline to Endpoint After 28 Days of Treatment. [Time Frame: Baseline and 28 days of treatment] [Designated as safety issue: No]

To explore the efficacy of mometasone furoate nasal spray in comparison with placebo in improving the quality of life of subjects with moderate-severe PER and intermittent asthma as measured by the Rhinasthma Questionnaire (Global Summary Score). The Rhinasthma is a questionnaire that consists of 30 items and for each of them subjects had to indicate on a Likert scale (1=not at all; 5=very much) the degree of limitation or discomfort caused by each problem. Possible total best score = 150 and possible total worst score = 30.

Enrollment:	51
Study Start Date:	May 2008
Study Completion Date:	May 2009
Primary Completion Date:	May 2009 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Mometasone furoate nasal spray Mometasone furoate nasal spray (MFNS) 200 mcg once daily (two 50 mcg puffs per nostril) in the morning.	Drug: Mometasone furoate nasal spray (MFNS) Mometasone furoate nasal spray (MFNS) 200 mcg once daily (two 50 mcg puffs per nostril) in the morning. Other Name: Nasonex Nasal Spray
Placebo Comparator: Placebo nasal spray Placebo nasal spray once daily (two puffs per nostril) in the morning.	Drug: Placebo nasal spray Placebo nasal spray once daily (two puffs per nostril) in the morning. Other Name: Placebo

Detailed Description:

The primary objective is to explore the efficacy of mometasone furoate nasal spray (MFNS) in comparison with placebo in improving the quality of life of subjects with moderate to severe persistent allergic rhinitis and intermittent asthma as measured by the Rhinasthma Questionnaire (Global Summary Score). In addition, there are two secondary objectives. The first secondary objective is to evaluate the efficacy of MFNS in improving the quality of life of subjects with moderate to severe persistent allergic rhinitis and intermittent asthma as measured by the Rhinasthma Upper Airways Score, the Rhinasthma Lower Airways Score, and the Rhinasthma Respiratory Allergy Impact Score. The second secondary objective is to evaluate the efficacy of MFNS in relieving the subject's symptoms of allergic rhinitis and asthma as measured by the Total 5 Symptoms Score (T5SS) and the Global Symptom Score (T5SS+asthma symptoms) and by the use of rescue medication on demand.

Eligibility

Ages Eligible for Study:	18 Years to 75 Years
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Outpatients (≥18 and ≤ 75 years of age) of either sex
- Willingness to participate and comply with procedures by signing a written informed consent
- Moderate/severe persistent allergic rhinitis with a history of intermittent asthma from at least 2 years and actual asthma (symptoms in the last 4 weeks)
- To qualify at the randomization visit the daily average of the T5SS [(Morning-time T5SS + Evening-time T5SS)/2] had to be ≥ 6 in at least 4 days during the 1 week run-in period
- Positive (weal diameter >3 mm) skin prick test (SPT) and/or CAP-RAST (class II or higher) performed in the 6 months prior to the start of the trial were required for at least house dust mite and 1 pollen allergen (grass or Parietaria, IgE level >3.5 U/mL)
- All prior medication washout times had been observed
- Female volunteers of childbearing potential had to agree to use a medically accepted method of contraception or be surgically sterilized prior to screening, while receiving protocol-specified medication, and for 30 days after stopping the medication
- Negative urine pregnancy test
- Free of any clinically relevant disease that would have interfered with study evaluations
- Able to adhere to the dosing and visit schedules, and agree to record symptom severity scores and use of IMP and rescue medications in a daily diary

Exclusion Criteria:

- Female who was or intended to become pregnant during the study or within 12 weeks after study completion

- Nursing, or intended to be nursing during the study or within 12 months after study completion
- Taking medications prohibited during the study or had not complied with the requirements for the designated washout periods for any of the prohibited medications
- Anatomical abnormalities of the nose (turbinate hypertrophy, septal deviation, polyps)
- Acute or chronic sinusitis currently being treated with antibiotics and/or topical or oral decongestants
- Rhinitis medicamentosa
- Evidence of persistent asthma, or asthma with daytime and nighttime symptoms not controlled by short-acting beta2-adrenoceptor agonists
- Asthma requiring chronic use of inhaled or systemic corticosteroids
- Upper respiratory tract or sinus infection that required antibiotic therapy and had not had at least a 14-day wash-out period prior to the run-in period, or had a viral upper respiratory infection within 7 days prior to screening
- Dependence on nasal, oral or ocular decongestants, nasal topical antihistamines, or nasal steroids
- Undergoing a progressive course of immunotherapy (hyposensitization). Subjects on a regular maintenance schedule prior to the screening visit were eligible for study inclusion; however, subject could not receive hyposensitization treatment within 24 hours prior to any study visit
- Diagnosed of cancer within the past 5 years (except for successfully treated basal and squamous cell carcinomas)
- Concomitant medical problem
- Had 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
- Smoked or had smoked within the previous 6 months
- Member of the staff, affiliated with, or family member of the staff personnel directly involved with this study
- Previously randomized into this study
- Any other clinically significant deviation from normal in the physical examination or medical history that could interfere with the study evaluation or affect subject safety
- In a situation or condition that could interfere with participation in the study
- Used any drug or device in an investigational protocol in the 30 days prior to visit 1
- Participating in other clinical studies
- Allergic or has sensitivity to the study drug or its excipients
- Compromised ability to provide informed consent
- History of non-compliance with medication or treatment protocols

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:

Baiardini I, Villa E, Rogkakou A, Pellegrini S, Bacic M, Compalati E, Braido F, Le Grazie C, Canonica GW, Passalacqua G. Effects of mometasone furoate on the quality of life: a randomized placebo-controlled trial in persistent allergic rhinitis and intermittent asthma using the Rhinasthma questionnaire. Clin Exp Allergy. 2011 Mar;41(3):417-23. doi: 10.1111/j.1365-2222.2010.03660.x. Epub 2010 Dec 1.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00599027 History of Changes
Other Study ID Numbers:	P05277
Study First Received:	January 10, 2008
Results First Received:	April 8, 2010
Last Updated:	March 27, 2015
Health Authority:	Italy: Ethics Committee

Additional relevant MeSH terms:

Asthma	Otorhinolaryngologic Diseases
Rhinitis	Respiratory Hypersensitivity

Bronchial Diseases
Hypersensitivity
Hypersensitivity, Immediate
Immune System Diseases
Lung Diseases
Lung Diseases, Obstructive
Nose Diseases
Respiratory Tract Diseases
Respiratory Tract Infections
Mometasone furoate
Anti-Allergic Agents
Anti-Inflammatory Agents
Pharmacologic Actions
Therapeutic Uses

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Results First Received: April 8, 2010

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator, Outcomes Assessor); Primary Purpose: Treatment
Conditions:	Allergic Rhinitis Asthma
Interventions:	Drug: Mometasone furoate nasal spray (MFNS) Drug: Placebo nasal spray

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 (MFNS) 200 mcg once daily (two 50 mcg puffs per nostril) in the morning.
Placebo Nasal Spray	Placebo nasal spray once daily (two puffs per nostril) in the morning.

Participant Flow: Overall Study

	Mometasone Furoate Nasal Spray	Placebo Nasal Spray
STARTED	**26**	**25**
COMPLETED	**25**	**22**
NOT COMPLETED	**1**	**3**
Withdrawal by Subject	**1**	**1**
Adverse Event	**0**	**1**
Treatment Failure	**0**	**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 (MFNS) 200 mcg once daily (two 50 mcg puffs per nostril) in the morning.
Placebo Nasal Spray	Placebo nasal spray once daily (two puffs per nostril) in the morning.
Total	Total of all reporting groups

Baseline Measures

	Mometasone Furoate Nasal Spray	Placebo Nasal Spray	Total
Number of Participants [units: participants]	**26**	**25**	**51**
Age [units: years] Mean (Standard Deviation)	**40.5 (13.42)**	**43.0 (16.62)**	**41.7 (14.97)**
Gender [units: participants]			
Female	**11**	**12**	**23**
Male	**15**	**13**	**28**

Outcome Measures

1. Primary: The Change of the Rhinasthma Global Summary Score From Baseline to Endpoint After 28 Days of Treatment. [Time Frame: Baseline and 28 days of treatment]

Hide Outcome Measure 1

Measure Type	Primary
Measure Title	The Change of the Rhinasthma Global Summary Score From Baseline to Endpoint After 28 Days of Treatment.
Measure Description	To explore the efficacy of mometasone furoate nasal spray in comparison with placebo in improving the quality of life of subjects with moderate-severe PER and intermittent asthma as measured by the Rhinasthma Questionnaire (Global Summary Score). The Rhinasthma is a questionnaire that consists of 30 items and for each of them subjects had to indicate on a Likert scale (1=not at all; 5=very much) the degree of limitation or discomfort caused by each problem. Possible total best score = 150 and possible total worst score = 30.
Time Frame	Baseline and 28 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.
No text entered.

Reporting Groups

	Description
Mometasone Furoate Nasal Spray	Mometasone furoate nasal spray (MFNS) 200 mcg once daily (two 50 mcg puffs per nostril) in the morning.
Placebo Nasal Spray	Placebo nasal spray once daily (two puffs per nostril) in the morning.

Measured Values

	Mometasone Furoate Nasal Spray	**Placebo Nasal Spray**
Number of Participants Analyzed [units: participants]	**26**	**25**
The Change of the Rhinasthma Global Summary Score From Baseline to Endpoint After 28 Days of Treatment. [units: units on a scale] Mean (Standard Deviation)		
Baseline	**25.3 (10.03)**	**26.7 (18.89)**
Endpoint after 28 days of treatment	**-10.3 (7.15)**	**0.4 (12.32)**

Statistical Analysis 1 for The Change of the Rhinasthma Global Summary Score From Baseline to Endpoint After 28 Days of Treatment.

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	0.001

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Overall treatment effect tested using F-test(alpha=0.05;two-sided). Diff between least square means of the 2 groups calculated with two-sided 95% C.I
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Endpoint after 28 days of treatment

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 (MFNS) 200 mcg once daily (two 50 mcg puffs per nostril) in the morning.
Placebo Nasal Spray	Placebo nasal spray once daily (two puffs per nostril) in the morning.

Serious Adverse Events

	Mometasone Furoate Nasal Spray	Placebo Nasal Spray
Total, serious adverse events		
# participants affected / at risk	**0/26 (0.00%)**	**0/25 (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
Mometasone Furoate Nasal Spray	Mometasone furoate nasal spray (MFNS) 200 mcg once daily (two 50 mcg puffs per nostril) in the morning.
Placebo Nasal Spray	Placebo nasal spray once daily (two puffs per nostril) in the morning.

Other Adverse Events

	Mometasone Furoate Nasal Spray	Placebo Nasal Spray
Total, other (not including serious) adverse events		
# participants affected / at risk	**0/26 (0.00%)**	**0/25 (0.00%)**

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 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 45 days written notice to the sponsor prior to submission for publication or presentation to permit the sponsor to review copies of abstracts or manuscripts for publication.

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:

Baiardini I, Villa E, Rogkakou A, Pellegrini S, Bacic M, Compalati E, Braido F, Le Grazie C, Canonica GW, Passalacqua G. Effects of mometasone furoate on the quality of life: a randomized placebo-controlled trial in persistent allergic rhinitis and intermittent asthma using the Rhinasthma questionnaire. Clin Exp Allergy. 2011 Mar;41(3):417-23. doi: 10.1111/j.1365-2222.2010.03660.x. Epub 2010 Dec 1.

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