The Effects of Phenylephrine Compared With Those of Placebo and Pseudoephedrine on Nasal Congestion in Subjects With Seasonal Allergic Rhinitis (SAR)(P04579)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00276016

First received: January 11, 2006
Last updated: September 25, 2015
Last verified: September 2015
History of Changes

Purpose

This is a Phase 3, single-dose, investigator-blind, randomized, placebo-controlled, crossover study, conducted at a single site in Austria, outside of the normal grass pollen season. An allergic reaction will be induced by exposing subjects to grass pollen in the Vienna Challenge Chamber (VCC). Subjects will receive a single dose of each of the following treatments according to a randomization sequence: Phenylephrine 12 mg immediate-release capsule, pseudoephedrine 60 mg immediate-release tablet, and placebo capsule. There will be a minimum of a 5-day washout period between each treatment. Subjects will complete symptom evaluations throughout the study. The nasal decongestant effects of phenylephrine will be compared to those of placebo using the subjective symptom evaluations. The safety profile (adverse events and vital signs) of the treatments will also be evaluated.

Condition	Intervention	Phase
Rhinitis, Allergic, Seasonal	Drug: phenylephrine Drug: pseudoephedrine Drug: placebo	Phase 3

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Crossover Assignment
Masking: Single Blind (Investigator)
Primary Purpose: Treatment

Official Title: Crossover Study of the Decongestant Effect of Phenylephrine Compared With Placebo and Pseudoephedrine as Active Control in SAR Subjects Exposed to Pollen in the Vienna Challenge Chamber

Resource links provided by NLM:

MedlinePlus related topics: Hay Fever

Drug Information available for: Ephedrine Hydrochloride Phenylephrine Phenylephrine hydrochloride Pseudoephedrine Ephedrine sulfate

Pseudoephedrine hydrochloride Oxymetazoline Oxymetazoline hydrochloride

U.S. FDA Resources

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

Primary Outcome Measures:

- The Average Change From Baseline to Endpoint (6 Hours Post-dosing) in Nasal Congestion for Phenylephrine Compared With Placebo [Time Frame: Baseline to endpoint (6 hour period)] [Designated as safety issue: No]

  To evaluate the effect of phenylephrine 12-mg immediate-release capsule on nasal congestion in subjects with seasonal allergic rhinitis (SAR) who have been exposed to pollen for 6 hours in the Vienna Challenge Chamber (VCC). The average change from the Baseline was evaluated immediately before treatment start, over the first 6 hour post-dosing. The values for the scale are 0,1,2,3 for measure of symptoms, defined as 0-none, 1-mild, 2-moderate, 3-severe. They are subject-evaluated results.

Secondary Outcome Measures:

- The Average Change From Baseline to Endpoint (6 Hours Post-dosing) in Nasal Congestion for Pseudoephedrine and Placebo. [Time Frame: Baseline to endpoint (6 hour period)] [Designated as safety issue: No]

  To estimate the effect of a pseudoephedrine (PSE) 60 mg immediate release tablet on nasal congestion over a 6-hour observation period relative to placebo The values for the nasal congestion score scale are 0,1,2,3 for measure of symptoms, defined as 0-none, 1-mild, 2-moderate, 3-severe. They are subject-evaluated results.

Enrollment:	39
Study Start Date:	January 2006
Study Completion Date:	February 2006
Primary Completion Date:	February 2006 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Phenylephrine, Pseudoephedrine, Placebo Phenylephrine: Immediate-release 12 mg capsules for oral administration. Pseudoephedrine: 60 mg immediate-release tablets for oral administration. Placebo: Placebo capsules.	Drug: phenylephrine immediate-release 12 mg capsules for oral administration Drug: pseudoephedrine 60 mg immediate-release tablets for oral administration Drug: placebo placebo capsules
Experimental: Pseudoephedrine, Placebo, Phenylephrine Pseudoephedrine: 60 mg immediate-release tablets for oral administration. Placebo: Placebo capsules. Phenylephrine: Immediate-release 12 mg capsules for oral administration.	Drug: phenylephrine immediate-release 12 mg capsules for oral administration Drug: pseudoephedrine 60 mg immediate-release tablets for oral administration Drug: placebo placebo capsules
Experimental: Placebo, Phenylephrine, Pseudoephedrine Placebo: Placebo capsules. Phenylephrine: Immediate-release 12 mg capsules for oral administration. Pseudoephedrine: 60 mg immediate-release tablets for oral administration.	Drug: phenylephrine immediate-release 12 mg capsules for oral administration Drug: pseudoephedrine 60 mg immediate-release tablets for oral administration Drug: placebo placebo capsules
Experimental: Phenylephrine, Placebo, Pseudoephedrine Phenylephrine: Immediate-release 12 mg capsules for oral administration. Placebo: Placebo capsules. Pseudoephedrine: 60 mg immediate-release tablets for oral administration.	Drug: phenylephrine immediate-release 12 mg capsules for oral administration Drug: pseudoephedrine 60 mg immediate-release tablets for oral administration Drug: placebo placebo capsules
Experimental: Pseudoephedrine, Phenylephrine, Placebo Pseudoephedrine: 60 mg immediate-release tablets for oral administration.	Drug: phenylephrine immediate-release 12 mg capsules for oral administration

Phenylephrine: Immediate-release 12 mg capsules for oral administration. Placebo: Placebo capsules.	Drug: pseudoephedrine 60 mg immediate-release tablets for oral administration Drug: placebo placebo capsules
Experimental: Placebo, Pseudoephedrine, Phenylephrine Placebo: Placebo capsules. Pseudoephedrine: 60 mg immediate-release tablets for oral administration. Phenylephrine: Immediate-release 12 mg capsules for oral administration.	Drug: phenylephrine immediate-release 12 mg capsules for oral administration Drug: pseudoephedrine 60 mg immediate-release tablets for oral administration Drug: placebo placebo capsules

Eligibility

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

Criteria

Inclusion Criteria:

- Skin test positive for the grass pollen allergen used in the chamber at Screening or within the prior 12 months.
- A negative urine pregnancy test at Screening and at monthly intervals for female subjects of childbearing potential.
- The following minimum scores at an evaluation time point during each of the 120-minute screening period challenge sessions:
  a. Nasal Congestion Score of at least 2 (moderate);
  b. Total Nasal Symptoms Score of at least 6;
  c. Total Non-nasal Symptoms Score of at least 2.
- Freedom from any clinically significant disease, other than SAR, that would interfere with the study evaluations.

Exclusion Criteria :

- An upper or lower respiratory tract infection within 4 weeks before Screening.
- Dependence upon nasal, oral, or ocular decongestants, nasal topical antihistamines, or nasal steroids, in the opinion of the investigator.
- A known potential for hypersensitivity, allergy, or idiosyncratic reaction to the study drug or excipients.

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

No publications provided by Merck Sharp & Dohme Corp.

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

Horak F, Zieglmayer P, Zieglmayer R, Lemell P, Yao R, Staudinger H, Danzig M. A placebo-controlled study of the nasal decongestant effect of phenylephrine and pseudoephedrine in the Vienna Challenge Chamber. Ann Allergy Asthma Immunol. 2009 Feb;102(2):116-20. doi: 10.1016/S1081-1206(10)60240-2.

Responsible Party: Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier: NCT00276016 History of Changes
Other Study ID Numbers: P04579
Study First Received: January 11, 2006
Results First Received: April 1, 2010

Last Updated:	September 25, 2015
Health Authority:	Austria: Federal Ministry for Health and Women

Additional relevant MeSH terms:

Rhinitis	Adrenergic Agonists
Rhinitis, Allergic, Seasonal	Adrenergic alpha-1 Receptor Agonists
Hypersensitivity	Adrenergic alpha-Agonists
Hypersensitivity, Immediate	Anti-Asthmatic Agents
Immune System Diseases	Autonomic Agents
Nose Diseases	Bronchodilator Agents
Otorhinolaryngologic Diseases	Cardiotonic Agents
Respiratory Hypersensitivity	Cardiovascular Agents
Respiratory Tract Diseases	Central Nervous System Agents
Respiratory Tract Infections	Central Nervous System Stimulants
Ephedrine	Molecular Mechanisms of Pharmacological Action
Oxymetazoline	Mydriatics
Phenylephrine	Nasal Decongestants
Pseudoephedrine	Neurotransmitter Agents
Adrenergic Agents	Peripheral Nervous System Agents

ClinicalTrials.gov processed this record on April 10, 2016

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

Results First Received: April 1, 2010

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Crossover Assignment; Masking: Single Blind (Investigator); Primary Purpose: Treatment
Condition:	Rhinitis, Allergic, Seasonal
Interventions:	Drug: phenylephrine Drug: pseudoephedrine Drug: placebo

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
No text entered.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
1 subject discontinued for reasons unrelated to treatment with study drug after the first dose (Intervention 1) of study drug Pseudoephedrine(PSE)

Reporting Groups

	Description
Phenylephrine, Pseudoephedrine, Placebo	Phenylephrine: Immediate-release 12 mg capsules for oral administration. Pseudoephedrine: 60

	mg immediate-release tablets for oral administration. Placebo: Placebo capsules
Pseudoephedrine, Placebo, Phenylephrine	Pseudoephedrine: 60 mg immediate-release tablets for oral administration. Placebo: Placebo capsules. Phenylephrine: Immediate-release 12 mg capsules for oral administration.
Placebo, Phenylephrine, Pseudoephedrine	Placebo: Placebo capsules. Phenylephrine: Immediate-release 12 mg capsules for oral administration. Pseudoephedrine: 60 mg immediate-release tablets for oral administration.
Phenylephrine, Placebo, Pseudoephedrine	Phenylephrine: Immediate-release 12 mg capsules for oral administration. Placebo: Placebo capsules. Pseudoephedrine: 60 mg immediate-release tablets for oral administration.
Pseudoephedrine, Phenylephrine, Placebo	Pseudoephedrine: 60 mg immediate-release tablets for oral administration. Phenylephrine: Immediate-release 12 mg capsules for oral administration. Placebo: Placebo capsules.
Placebo, Pseudoephedrine, Phenylephrine	Placebo: Placebo capsules. Pseudoephedrine: 60 mg immediate-release tablets for oral administration. Phenylephrine: Immediate-release 12 mg capsules for oral administration

Participant Flow for 5 periods

Period 1: Intervention 1

	Phenylephrine, Pseudoephedrine, Placebo	Pseudoephedrine, Placebo, Phenylephrine	Placebo, Phenylephrine, Pseudoephedrine	Phenylephrine, Placebo, Pseudoephedrine	Pseudoephedrine, Phenylephrine, Placebo	Placebo, Pseudoephedrine, Phenylephrine
STARTED	7	7	7	6	6	6
COMPLETED	7	6	7	6	6	6
NOT COMPLETED	0	1	0	0	0	0
Withdrawal by Subject	0	1	0	0	0	0

Period 2: Wash Out 1

	Phenylephrine, Pseudoephedrine, Placebo	Pseudoephedrine, Placebo, Phenylephrine	Placebo, Phenylephrine, Pseudoephedrine	Phenylephrine, Placebo, Pseudoephedrine	Pseudoephedrine, Phenylephrine, Placebo	Placebo, Pseudoephedrine, Phenylephrine
STARTED	7	6	7	6	6	6
COMPLETED	7	6	7	6	6	6
NOT COMPLETED	0	0	0	0	0	0

Period 3: Intervention 2

	Phenylephrine, Pseudoephedrine, Placebo	Pseudoephedrine, Placebo, Phenylephrine	Placebo, Phenylephrine, Pseudoephedrine	Phenylephrine, Placebo, Pseudoephedrine	Pseudoephedrine, Phenylephrine, Placebo	Placebo, Pseudoephedrine, Phenylephrine
STARTED	7	6	7	6	6	6
COMPLETED	7	6	7	6	6	6
NOT COMPLETED	0	0	0	0	0	0

Period 4: Wash Out 2

	Phenylephrine, Pseudoephedrine, Placebo	Pseudoephedrine, Placebo, Phenylephrine	Placebo, Phenylephrine, Pseudoephedrine	Phenylephrine, Placebo, Pseudoephedrine	Pseudoephedrine, Phenylephrine, Placebo	Placebo, Pseudoephedrine, Phenylephrine
STARTED	7	6	7	6	6	6
COMPLETED	7	6	7	6	6	6
NOT COMPLETED	0	0	0	0	0	0

Period 5: Intervention 3

	Phenylephrine, Pseudoephedrine, Placebo	Pseudoephedrine, Placebo, Phenylephrine	Placebo, Phenylephrine, Pseudoephedrine	Phenylephrine, Placebo, Pseudoephedrine	Pseudoephedrine, Phenylephrine, Placebo	Placebo, Pseudoephedrine, Phenylephrine
STARTED	7	6	7	6	6	6
COMPLETED	7	6	7	6	6	6
NOT COMPLETED	0	0	0	0	0	0

Baseline Characteristics

Hide Baseline Characteristics

Population Description

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

Reporting Groups

	Description
Phenylephrine, Pseudoephedrine, Placebo	Phenylephrine: Immediate-release 12 mg capsules for oral administration. Pseudoephedrine: 60 mg immediate-release tablets for oral administration. Placebo: Placebo capsules
Pseudoephedrine, Placebo, Phenylephrine	Pseudoephedrine: 60 mg immediate-release tablets for oral administration. Placebo: Placebo capsules. Phenylephrine: Immediate-release 12 mg capsules for oral administration.
Placebo, Phenylephrine, Pseudoephedrine	Placebo: Placebo capsules. Phenylephrine: Immediate-release 12 mg capsules for oral administration. Pseudoephedrine: 60 mg immediate-release tablets for oral administration.
Phenylephrine, Placebo, Pseudoephedrine	Phenylephrine: Immediate-release 12 mg capsules for oral administration. Placebo: Placebo capsules. Pseudoephedrine: 60 mg immediate-release tablets for oral administration.
Pseudoephedrine, Phenylephrine, Placebo	Pseudoephedrine: 60 mg immediate-release tablets for oral administration. Phenylephrine: Immediate-release 12 mg capsules for oral administration. Placebo: Placebo capsules.
Placebo, Pseudoephedrine, Phenylephrine	Placebo: Placebo capsules. Pseudoephedrine: 60 mg immediate-release tablets for oral administration. Phenylephrine: Immediate-release 12 mg capsules for oral administration
Total	Total of all reporting groups

Baseline Measures

	Phenylephrine, Pseudoephedrine, Placebo	Pseudoephedrine, Placebo, Phenylephrine	Placebo, Phenylephrine, Pseudoephedrine	Phenylephrine, Placebo, Pseudoephedrine	Pseudoephedrine, Phenylephrine, Placebo	Placebo, Pseudoephedrine, Phenylephrine	Total
Number of Participants [units: participants]	7	7	7	6	6	6	39
Age, Customized [units: years] Mean (Standard Deviation)	27.9 (9.0)	27.9 (3.3)	24.9 (3.5)	26.3 (1.6)	28.0 (7.1)	27.3 (3.3)	27.0 (5.1)
Gender [units: participants]							
Female	5	5	4	1	3	5	23
Male	2	2	3	5	3	1	16

Outcome Measures

Hide All Outcome Measures

1. Primary: The Average Change From Baseline to Endpoint (6 Hours Post-dosing) in Nasal Congestion for Phenylephrine Compared With Placebo [Time Frame: Baseline to endpoint (6 hour period)]

Measure Type	Primary
Measure Title	The Average Change From Baseline to Endpoint (6 Hours Post-dosing) in Nasal Congestion for Phenylephrine Compared With Placebo
Measure Description	To evaluate the effect of phenylephrine 12-mg immediate-release capsule on nasal congestion in subjects with seasonal allergic rhinitis (SAR) who have been exposed to pollen for 6 hours in the Vienna Challenge Chamber (VCC). The average change from the Baseline was evaluated immediately before treatment start, over the first 6 hour post-dosing. The values for the scale are 0,1,2,3 for measure of symptoms, defined as 0-none, 1-mild, 2-moderate, 3-severe. They are subject-evaluated results.
Time Frame	Baseline to endpoint (6 hour period)
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
Placebo	No text entered.
Phenylephrine	No text entered.

Measured Values

	Placebo	Phenylephrine

Number of Participants Analyzed [units: participants]	**38**	**38**
The Average Change From Baseline to Endpoint (6 Hours Post-dosing) in Nasal Congestion for Phenylephrine Compared With Placebo [units: Units on a scale] Mean (Standard Deviation)		
Baseline score	**2.20 (0.36)**	**2.20 (0.36)**
Change from Baseline to Endpoint Score	**-0.12 (0.44)**	**-0.18 (0.44)**

Statistical Analysis 1 for The Average Change From Baseline to Endpoint (6 Hours Post-dosing) in Nasal Congestion for Phenylephrine Compared With Placebo

Groups [1]	All groups
Method [2]	ANOVA
P Value [3]	0.561

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	For endpoint
[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: The Average Change From Baseline to Endpoint (6 Hours Post-dosing) in Nasal Congestion for Pseudoephedrine and Placebo. [Time Frame: Baseline to endpoint (6 hour period)]

Measure Type	Secondary
Measure Title	The Average Change From Baseline to Endpoint (6 Hours Post-dosing) in Nasal Congestion for Pseudoephedrine and Placebo.
Measure Description	To estimate the effect of a pseudoephedrine (PSE) 60 mg immediate release tablet on nasal congestion over a 6-hour observation period relative to placebo The values for the nasal congestion score scale are 0,1,2,3 for measure of symptoms, defined as 0-none, 1-mild, 2-moderate, 3-severe. They are subject-evaluated results.
Time Frame	Baseline to endpoint (6 hour period)
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
Pseudoephedrine	No text

	entered.
Placebo	No text entered.

Measured Values

	Pseudoephedrine	Placebo
Number of Participants Analyzed [units: participants]	**39**	**38**
The Average Change From Baseline to Endpoint (6 Hours Post-dosing) in Nasal Congestion for Pseudoephedrine and Placebo. [units: Units on a scale] Mean (Standard Deviation)		
Baseline	**2.26 (0.36)**	**2.20 (0.36)**
Endpoint	**-0.47 (0.44)**	**-0.12 (0.44)**

Statistical Analysis 1 for The Average Change From Baseline to Endpoint (6 Hours Post-dosing) in Nasal Congestion for Pseudoephedrine and Placebo.

Groups [1]	All groups
Method [2]	ANOVA
P Value [3]	<.001

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	For endpoint
[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
Phenylephrine	Phenylephrine: Immediate-release 12 mg capsules for oral administration.
Pseudoephedrine	Pseudoephedrine: 60 mg immediate-release tablets for oral administration.

Placebo	Placebo: Placebo capsules.

Serious Adverse Events

	Phenylephrine	Pseudoephedrine	Placebo
Total, serious adverse events			
# participants affected / at risk	**0/39 (0.00%)**	**0/39 (0.00%)**	**0/39 (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
Phenylephrine	Phenylephrine: Immediate-release 12 mg capsules for oral administration.
Pseudoephedrine	Pseudoephedrine: 60 mg immediate-release tablets for oral administration.
Placebo	Placebo: Placebo capsules.

Other Adverse Events

	Phenylephrine	Pseudoephedrine	Placebo
Total, other (not including serious) adverse events			
# participants affected / at risk	**0/39 (0.00%)**	**0/39 (0.00%)**	**0/39 (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:

- [x] 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.

Results Point of Contact:

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

No publications provided by Merck Sharp & Dohme Corp.

Publications automatically indexed to this study:

Horak F, Zieglmayer P, Zieglmayer R, Lemell P, Yao R, Staudinger H, Danzig M. A placebo-controlled study of the nasal decongestant effect of phenylephrine and pseudoephedrine in the Vienna Challenge Chamber. Ann Allergy Asthma Immunol. 2009 Feb;102(2):116-20. doi: 10.1016/S1081-1206(10)60240-2.

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