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Effects of AkPharma's Calcium Glycerophosphate Nasal Spray Wash

This study has been completed.

Sponsor:

Drexel University

Collaborator:

AkPharma Inc.

Information provided by (Responsible Party):

Edward Schulman, Drexel University

ClinicalTrials.gov Identifier:

NCT01647633

First received: July 19, 2012

Last updated: May 21, 2015

Last verified: May 2015

History of Changes

- Full Text View
- Tabular View
- No Study Results Posted
- Disclaimer
- How to Read a Study Record

Purpose

Over 20 million Americans have allergic nasal symptoms including stuffiness, sneezing and a "runny" nose. AkPharma's Calcium Glycerophosphate used as a nasal spray wash is believed to improve these

symptoms without side effects common to over the counter and prescription medication. It is hypothesized that Calcium Glycerophosphate will have a perceived improvement in breathing comfort.

Condition	Intervention	Phase
Allergic Rhinitis	Other: Calcium Glycerophosphate Nasal Spray Wash	Phase 1 Phase 2

Study Type: Interventional

Study Design: Intervention Model: Single Group Assignment
Masking: Open Label
Primary Purpose: Treatment

Official Title: Effects of AkPharma's Calcium Glycerophosphate Nasal Spray Wash on Patient-Perceived Breathing Comfort

Resource links provided by NLM:

MedlinePlus related topics: Calcium

Drug Information available for: Calcium Gluconate

U.S. FDA Resources

Further study details as provided by Drexel University:

Primary Outcome Measures:

- Nasal Symptom Diary [Time Frame: 28 days]

  Perceived improved comfort breathing is anticipated as primary outcome

Secondary Outcome Measures:

- Spirometry [Time Frame: 21 days]

  Anticipate change in spirometry

Enrollment: 17

Study Start Date: May 2012

Study Completion Date: May 2015

Primary Completion Date: April 2015 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Calcium Glycerophosphate Nasal Wash Nasal spray wash twice daily and up to four additional times per day as needed for nasal allergy symptoms	Other: Calcium Glycerophosphate Nasal Spray Wash Nasal wash two to six times per day

Detailed Description:

Subjects will be screened for inclusion and exclusion criteria and consented if they fit the same criteria. They will be instructed on keeping a nasal diary of symptoms "runny, itchy, congestion, sneezing, voice changes and throat clearing". They will have blood drawn for allergy testing. After a 1 week run-in, subjects will return their diary. If they still qualify based on the diary they will have baseline labs drawn and baseline breathing test (Spirometry) performed. They will also have a nasal wash and specimen collection performed. They will be instructed on use of the nasal wash. There will be three more weekly visits before study conclusion which will include diary submission, Spirometry and nasal wash and specimen collection. On the final visit blood will again be collected as well.

Eligibility

Ages Eligible for Study: 18 Years to 80 Years (Adult, Senior)

Sexes Eligible for Study: All

Accepts Healthy Volunteers: Yes

Criteria

Inclusion Criteria:

- Male or Female 18-80 years of age
- Twelve months or more of allergic rhinitis symptoms
- Allergic antibodies to perennial aeroallergens to be confirmed by blood draw

Exclusion Criteria:

- Intranasal or systemic glucocorticosteroids within one month of study entry
- Intranasal cromolyn for 2 weeks prior to study
- Intranasal or systemic antihistamine for 3 days prior to the study
- Loratadine for ten days prior to study
- History of rhinitis medicamentosa
- Planned travel outside the study area that will inhibit study follow-up visits

  _Persons with Asthma with more than 2 episodes per week or month of nighttime awakenings
- Persons with Known sensitivity to Calcium or phosphorus supplements
- Persons taking antihistamine treatment intermittently. (Chronic steady use throughout study is acceptable)
- Immunomodulatory or cytotoxic drugs
- Clinically significant uncontrolled disease that in the opinion of the investigator would put the subject at risk or may confound the study interpretation
- Persons with hypercalcemia
- Persons whose nasal obstruction(s) would be significant to obstruct air flow
- Persons who are employees of Investigator or AkPharma or whose spouse, parent, child or sibling is employee of investigator
- Pregnant persons or persons planning to conceive/inseminate partner during study or for one month after

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: NCT01647633

Locations

United States, Pennsylvania

Drexel University College of Medicine

Philadelphia, Pennsylvania, United States, 19102

Sponsors and Collaborators

Drexel University

AkPharma Inc.

Investigators

Principal Investigator: Edward S Schulman, MD Drexel University College of Medicine

More Information

Responsible Party: Edward Schulman, MD, PI, Drexel University

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Other Study ID Numbers: AkP 010112A

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Keywords provided by Drexel University:

rhinitis
stuffy nose
congestion
Sneezing

Additional relevant MeSH terms:

Rhinitis
Rhinitis, Allergic
Hypersensitivity, Immediate
Hypersensitivity

Nose Diseases
Respiratory Tract Diseases
Respiratory Tract Infections
Otorhinolaryngologic Diseases
Respiratory Hypersensitivity
Immune System Diseases
Calcium, Dietary
Bone Density Conservation Agents
Physiological Effects of Drugs

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