Fenzian Asthma Multicenter Outcomes Study (FAMOUS)

This study is currently recruiting participants.

Verified by University of California, Los Angeles, May 2010

First Received: November 3, 2008 Last Updated: May 14, 2010 History of Changes

Sponsor:	University of California, Los Angeles
Collaborator:	Eumedic Ltd.
Information provided by:	University of California, Los Angeles
ClinicalTrials.gov Identifier:	NCT00784758

Purpose

The purpose of this study is to investigate the effects of Fenzian™ treatment on symptoms (such as shortness of breath), lung function (how well the lungs work), and albuterol/salbutamol (rescue medication) use in people with asthma. This will be done by comparing the effects of Fenzian™ treatment to the effects of a sham treatment, which looks the same as the Fenzian™ device but doesn't do anything.

The Fenzian™ device is an electrical instrument that the investigators hope will help reduce airway inflammation associated with asthma symptoms by stimulating the nerves with very low electrical currents. The study device will be applied directly to the skin on the back, working along the ribs toward the spine, alternating between left and right sides, and on your face.

Condition	Intervention
Asthma	Device: Fenzian Device Device: Sham Device

Study Type: Interventional

Study Design: Allocation: Randomized
Control: Placebo Control
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Parallel Assignment

Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor)
Primary Purpose: Treatment

Official Title: Effect of Fenzian™ Treatment on Symptoms, Pulmonary Function and Albuterol/Salbutamol Use in Patients With Mild to Moderate Persistent Asthma: A Multicenter, Sham-Controlled Clinical Trial

Resource links provided by NLM:

MedlinePlus related topics: Asthma Breathing Problems

U.S. FDA Resources

Further study details as provided by University of California, Los Angeles:

Primary Outcome Measures:

- Change in Asthma Control Questionnaire 7 score [Time Frame: 5 weeks] [Designated as safety issue: No]

Secondary Outcome Measures:

- Change in Asthma Control Test score [Time Frame: 5 weeks]
  [Designated as safety issue: No]
- Change in spirometry (FEV1, FVC, FEF25-75%, isovolume FEF25-75%), and daily peak expiratory flow (AM, PM, daily amplitude variability) [Time Frame: 5 weeks]
  [Designated as safety issue: No]
- Change in exhaled nitric oxide (NO) (to evaluate airway inflammation) (at selected sites only) [Time Frame: 5 weeks]
  [Designated as safety issue: No]
- Change in symptoms, use of short-acting bronchodilator and peak expiratory flow [Time Frame: 5 weeks]
  [Designated as safety issue: No]
- Change in Asthma Quality of Life Questionnaire (AQLQ) score (to evaluate Quality of life) [Time Frame: 5 weeks]
  [Designated as safety issue: No]
- Change in Mahler transitional dyspnea index (TDI) score (to evaluate breathlessness) [Time Frame: 5 weeks]
  [Designated as safety issue: No]

Estimated Enrollment:	125
Study Start Date:	February 2009
Estimated Study Completion Date:	February 2011
Estimated Primary Completion Date:	February 2011 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Fenzian Device: Experimental Subjects randomized to this arm will receive treatment with the Fenzian Device	Device: Fenzian Device Three 20-minute treatments with the Fenzian Device per week for 5 weeks (for a total of 15 treatments)
Sham Device: Sham Comparator Subjects randomized to this arm will receive treatment with the sham device.	Device: Sham Device Three 20-minute treatments with the sham device per week for 5 weeks (for a total of 15 treatments) (NOTE: This arm is similar to a placebo arm in a drug trial.)

Eligibility

Ages Eligible for Study: 12 Years to 80 Years
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Ages 12-80 years. [NOTE: Only the Johns Hopkins site will enroll subjects under 18.]
- Clinical history consistent with asthma (GINA 4 definitions) for at least six months
- Current symptoms and features of partly-controlled or uncontrolled asthma, according to GINA classification of asthma control
- A stable (1 month) treatment regimen consisting of:
    - as needed short-acting bronchodilators alone,
    - as needed short-acting bronchodilators in combination with low- or medium-dose inhaled corticosteroids (<= 1000 mcg per day beclomethasone or equivalent,

    - any combination of long acting beta-agonist bronchodilator and low- or medium-dose inhaled corticosteroid (as defined above),as needed short-acting bronchodilators in combination with montelukast or other leukotriene modifier
- Willingness to comply with the study protocol and ability to perform the study procedures.
- Willingness to attend the study site according to the specified treatment schedule

Inclusion Criteria Assessed at Visit 1:

- Pre-bronchodilator FEV1 between 60% predicted and the lower limit of normal.
- Pre-bronchodilator FEV1/FVC less than the lower limit of normal.
- Reversibility of FEV1 of at least 200 ml, 15-20 minutes after 4 puffs of albuterol HFA pressurized metered-dose inhaler pMDI.

Inclusion Criteria Assessed at Visit 2:

- Reversibility of FEV1 of at least 200ml, 15-30 minutes after 4 puffs of albuterol HFA pMDI if not confirmed at Visit 1 plus
- Using short-acting bronchodilator therapy on two or more occasions in each of the two weeks preceding Visit 2 plus (Ventolin HFA counter decrease of at least 8 puffs)
- Partly controlled or uncontrolled of asthma as indicated by one to three, but not four of the following in each of the two weeks preceding Visit 2:
    - Daytime symptoms more than twice per week
    - Any limitation of activity
    - Any nocturnal symptoms or awakening
    - PEF<80% of predicted on any day

Exclusion Criteria:

- Pulmonary disease other than asthma, such as smoking-related COPD, clinically significant bronchiectasis, lung resection, and interstitial lung disease.
- Other significant systemic illness which might, in the opinion of the investigator alter the risk or outcome of the study (e.g. cardiovascular arrhythmias or conduction abnormalities, hyperthyroidism, uncontrolled hypertension, cancer)
- Tobacco smoking greater than 10 pack-year of cumulative exposure or current smoking within 10 years.
- Respiratory tract infection within 6 weeks of the study.

- Seasonal allergies causing symptoms within the past 4 weeks. Perennial or out of season allergic rhinitis is acceptable. Nasal corticosteroids and long-acting antihistamines are acceptable.
- Any investigational drug or treatment within 30 days.
- Use of cromolyn, nedocromil, theophylline, tiotropium, or oral albuterol within 1 week prior to Visit 1 of the study.
- Current use of omalizumab or within the last 8 weeks.
- Subjects on anti-depressant (mono-amine oxidase inhibitors or tricyclic antidepressants) treatment within 8 weeks.
- Non-potassium sparing diuretics unless in fixed combination with potassium sparing diuretics within one week.
- Digoxin, within one week, unless levels have been monitored previously while taking albuterol or LABAs.
- Presence of an implanted cardiac pacemaker or neurostimulator. A removable transcutaneous nerve stimulator, not used during the treatment sessions is acceptable.
- Non-selective beta agonists. (acceptable choices include: bisproprolol, betaxolol, atenolol, acebutolol and metoprolol)
- Subjects who are pregnant or breast feeding.
- Persons employed by or related to those employed by the investigative site (e.g. Pulmonary Division).
- Prior Fenzian treatment for any indication
- Hypersensitivity or intolerance of albuterol HFA pMDI (Ventolin) or its components. Note: if the subject is using ipratropium bromide for rescue short-acting bronchodilator, they must specifically not have been placed on that treatment due to intolerance of albuterol/salbutamol.
- Inability to withhold, before and during each visit (except the initial consent visit), xanthine-containing foods (coffee, tea, cola, chocolate, etc.) and alcohol for 6 hours, and short-acting bronchodilators for 8 hours.
- Unwillingness to stop use of non-study supplied albuterol (nebulized, CFC or HFA), other short-acting beta agonists (e.g. epinephrine, levalbuterol, metaproterenol, pirbuterol, terbutaline) and ipratropium during the study (after consent through visit 4).
- Inability to coordinate the timing for doses of long-acting beta agonists (withhold period at least 12 hours prior to visit) with Visits 1, 2, 3 or 4

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT00784758

Locations

United States, California

University of California, Los Angeles **Recruiting**
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United States, Maryland

Johns Hopkins University **Recruiting**
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Contact: Pranoti Pradhan 443-287-4163 ppradha1@jhmi.edu
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Sub-Investigator: Meredith McCormack, MD, MHS
Sub-Investigator: Nadia Hansel, MD, MPH

United States, North Carolina

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Sub-Investigator: Gregory Metz, MD

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Sub-Investigator: Mary E Bateman, MD
Sub-Investigator: G Fatti, MD
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United Kingdom, Cambridgeshire

Addenbrookes NHS Trust, Cambridge University **Recruiting**
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Contact: Jacqui Galloway 07919053911 jgalloway@cambridge-clinical-research.co.uk
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Principal Investigator: Neil Barnes, MD

Sponsors and Collaborators
University of California, Los Angeles
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Investigators

Principal Investigator:	Christopher B Cooper, M.D.	University of California, Los Angeles

More Information

No publications provided

Responsible Party:	UCLA (Christopher B. Cooper, M.D.)
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Other Study ID Numbers:	Fenzian
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Last Updated:	May 14, 2010
Health Authority:	United States: Institutional Review Board; South Africa: Medicines Control Council; United Kingdom: Research Ethics Committee

Keywords provided by University of California, Los Angeles:
Asthma
Lung Diseases
Respiratory Tract Diseases

Additional relevant MeSH terms:

Asthma	Respiratory Hypersensitivity
Bronchial Diseases	Hypersensitivity, Immediate
Respiratory Tract Diseases	Hypersensitivity
Lung Diseases, Obstructive	Immune System Diseases
Lung Diseases	

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