

A NEW PATH
MAY BE OPENING
FOR ASTHMA SUFFERERS.

Objective:

To demonstrate the effectiveness and safety of a new investigational outpatient procedure, Bronchial Thermoplasty™ with the Alair® System, for the treatment of asthma.

Design:

An international, multi-center, randomized, double blind, sham—controlled study comparing the effects of treatment with the Alair System to conventional drug therapy with diagnostic bronchoscopy.

Description:

The Control Group will continue with their prescribed medications and they will undergo three outpatient diagnostic bronchoscopy sessions.

The Treatment Group will also continue with their prescribed medications but they will also have their airways treated with the Alair System during the three bronchoscopy sessions.

Possible benefits:

Early clinical results in a non-randomized trial showed a persistent reduction in airway responsiveness, as measured by methacholine challenge, at 12 weeks. Results show a persistent reduction of hyperresponsiveness, on average out to two years.

AIR TRIAL

Asthma Intervention Research 2 Trial

Patients may call 1-866-400-AIR2 for more information.

The FDA KEEPS WATCH

In order for a drug to be made available to you, it must go through the complete clinical research process successfully and be approved for use. The federal agency in charge of the testing and approval process is the Food and Drug Administration (FDA), a part of the U.S. Department of Health and Human Services.

Here are ways the FDA helps you:

- Ensures that the drugs you take are safe and effective.
- Inspects and approves the plans (protocols) for clinical research studies.
- Protects study volunteers by ensuring that all research is held to specific standards.
- Evaluates and approves the final results when studies are complete.
- Approves the product for the public.
- Serves as a resource for more information about clinical research studies.

Learn more online at: www.fda.gov.

To learn more about clinical research studies,
call Veritas Clinical Specialties at 785-354-0735.

FOREsite
PUBLISHING, INC.
www.fspi.info

FOREsite
PUBLISHING, INC.

ForeWard™



Restless Legs and Restless Nights?

Join our RLS Research Study. We are looking for adults to participate in a clinical research study testing an investigational, longer-acting form of a marketed drug in patients with nighttime/evening symptoms of Restless Legs Syndrome (RLS) and associated sleep disturbance.

You may be eligible to participate if you:

- Are 18-79 years old
- Have been diagnosed with RLS and do not require treatment for symptoms before 6pm
- Have a usual bedtime of 8:30 pm to 12:30 am
- Have sleep disturbance due to RLS
- Are willing to stop taking other medications for the treatment of RLS or sleep during participation in the study

Study participation lasts up to 16 weeks and requires 4 clinic visits and 5 overnight visits. All study-related office visits, medical evaluations, and study medication will be provided to qualified study participants at no cost. For more information, please contact: 785-354-0735

Veritas

Healthcare Research Changing Lives

515 SW Home St. Suite 200
Topeka, KS 66606
785-354-0735

www.verispecial.com

Winter 2007

ForeWard™

Research Today for Better Care Tomorrow

What Is a Protocol?



Protocols must state:

- What types of people may take part in the trial, based on factors such as age, gender, medical condition, etc.;
- The schedule

- What data will be collected by the research team.

Every detail of the study is approved by a group of clinical research experts, called an Institutional Review Board (IRB), before it can begin. The group is independent of the study, the principal investigator, and the sponsor. The role of the IRB is to ensure the safety and protection of all study volunteers.

All clinical research studies follow a detailed plan called a *protocol*. The *protocol* indicates what specific research questions the study will try to answer (the study hypothesis) and exactly how the study will be conducted.

The importance of the *protocol* is to ensure that all research sites are treating all volunteers in the exact same manner. This consistency allows the hypothesis to be answered with certainty.

of tests or procedures a volunteer will undergo;

- What product is being studied and what, if anything, it is being compared to;
- What the potential risks and benefits are;
- How many times the volunteers will be seen by the research study staff;
- How long the study will last; and

The importance of the *protocol* is to ensure that all research sites are treating all volunteers in the exact same manner.

volunteer's voice

It's such a simple thing to do



For Rose Weidner, the pain of fibromyalgia comes and goes.

"For periods of time, I feel fine," Weidner explains. "And then when the pain comes, it can be a raging flare-up."

The 54-year-old from Columbia, Md., has learned to live with pain, as she has tried several different treatment options with intermittent success. When her doctor suggested she consider volunteering for a clinical research study to test a new drug for fibromyalgia, Weidner agreed. Because her sister is a researcher, Weidner understands how such studies are done, but she had never personally participated in one before. She had her share of questions before she made her final decision.

"I didn't seek out a research study, but when my doctor contacted me, I wanted to learn more," Weidner says. "The study was very well explained to me—the entire method and all the possible side effects. All my questions were answered, and I knew I was able to end my participation at any time if I wanted to."

Weidner has experienced some relief from her pain since she started participating in her clinical research study in January. She had a few side effects initially that she describes as "annoying more than anything else," but says the benefits outweigh them. And she is committed to remaining in the one-year study.

"It's really important to volunteer," Weidner says. "It's such a simple thing for me to do. It's not just for my benefit, but for the general benefit it can bring to others."

A potential new treatment for emphysema

"I used to take breathing for granted. Now, after years of smoking, I've developed emphysema and every breath is hard work"

—An emphysema patient

The EASE™ Trial

CLINICAL RESEARCH STUDY RECRUITING PATIENTS

Research teams across the US are currently recruiting patients for a clinical trial evaluating the safety and efficacy of a new treatment, called the Airway Bypass procedure to improve pulmonary function and breathlessness in patients with advanced widespread emphysema.

Participation covers medical care at no charge to you, including:

- Supervised pulmonary rehabilitation therapy
- Enrollment in the EASE Trial investigational study
- All follow-up visits related to the trial

You may qualify for the EASE research trial if you:

- Are age 35 years or older
- Have been diagnosed with advanced widespread emphysema
- Have stopped smoking for at least 2 months before you enter the trial

For more information call: 1-785-354-0735
or visit www.easetrialus.com

Helping to Create the Newest Treatments in Medical Care



William Leeds, DO

William Leeds, DO, finds clinical research hard to resist.

"As a physician, it is difficult not to be interested in clinical research," he explains. "The allure of working with the newest therapies is irresistible."

Dr. Leeds has been involved in clinical research for about 18 years. He has remained active and committed for so long because he sees benefits both for himself professionally and for patients.

"I feel that not only are we helping patients, but those of us participating have all become better clinicians as well," he says.

Dr. Leeds and his research team specialize in studies of pulmonary diseases (diseases of the lung), sleep disorders, and critical care medicine. He has seen many new and exciting developments in these areas as a result of clinical research.

"At last there are minimally invasive techniques available to treat asthma and emphysema through device research, which we have been an integral part of," Dr. Leeds says. "There are also cutting edge treatments for insomnia and sepsis [infection of the blood stream], as well."

Throughout his years in clinical research, Dr. Leeds has met countless study volunteers, people he describes as "amazing." Without them, he notes, there would be no clinical research, no medical advances.

"The people that we have worked with who have volunteered for clinical studies are truly amazing people," he says. "The vast majority are most concerned with their contribution to science and helping future generations."



Are You African American and Have Trouble Breathing?



If you are a smoker or ex-smoker and are having trouble breathing, you may qualify for a clinical research study for an investigational medication that could help manage your symptoms. Qualified participants will receive study-related medical care, physical exams, lab tests and the study drug at no cost.

According to the World Health Organization, Chronic Obstructive Pulmonary Disease (COPD) is the fourth leading cause of death worldwide. COPD is a slow, progressive disease of the airways characterized by a gradual loss of lung function; the condition includes emphysema and chronic

bronchitis. In the U.S. alone it is estimated that over 14 million Americans have COPD. Many cases are undiagnosed, as substantial loss of lung function can occur prior to the onset of symptoms. Cigarette smoking causes most cases of COPD.

If you are concerned about your breathing problem call the Veritas Clinical Specialists at (785) 354-0735 today to see if you qualify.

Veritas Clinical Specialists
(785) 354-0735

**Research Study
With Dr. William Leeds**

- Do you have Pulmonary Hypertension?
- Do you have Chronic Obstructive Pulmonary Disease (COPD)?

There is a Research study of an Investigational drug for the treatment of Pulmonary Hypertension associated with Chronic Obstructive Pulmonary Disease (COPD)

About the study:

- This is a study of an investigational drug (not approved by the Food and Drug Administration - FDA)
- The study is up to 8-9 weeks long

Some Study Requirements:

- You must have a history of COPD and High Blood Pressure in your Lungs (Pulmonary Hypertension)
- You must be 25-79 years old
- You must have a history of smoking for at least 10 years
- You cannot have participated in another research study of an investigational drug in the past 30 days.



If you wish to know more about this research study, please ask the study doctor for information:

Dr. William Leeds
515 SW Horne
Topeka, Kansas 66606
785-354-0735

To learn more about clinical research studies, call Veritas Clinical Specialists at 785-354-0735.