DID YOU KNOW THAT?

- Lung cancer is the leading cause of cancer death in both sexes. It kills more people than cancers of the breast, prostate, colon, and pancreas combined.
- Cigarette smoking accounts for nearly 90% of all lung cancers and is therefore one of the most preventable causes of death from cancer. The majority of lung cancers in the US are diagnosed in former smokers; after quitting many smokers remain at high risk for developing lung cancer.
- Lung cancer continues to be the most deadly of all human cancers, and is expected to account for 157,300 deaths in 2010.
- Cancer prevention research has led to progress against lung cancer and our knowledge is ever increasing.

No treatment has been shown to prevent lung cancer. Doctors at the Denver VA Medical Center and University of Colorado are interested in learning if a new drug called inhaled iloprost (Ventavis®) might reverse some of the lung cell changes associated with future development of lung cancer in patients who are former smokers and at high risk for lung cancer.

We are doing this by looking at the cells inside the lungs of smokers for early changes that might eventually lead to the development of lung cancer. We are testing to see if inhaled iloprost can stop these cells from turning into lung cancer.

We are looking for volunteers to help us with this research.

WHAT IS THE NAME OF THE TRIAL?

The trial is called, “A Phase I Trial of Inhaled Iloprost for the Prevention on Lung Cancer in Former Smokers” (COMIRB #14-1247). It is sponsored by a grant from the National Cancer Institute.

WHAT WILL PARTICIPANTS BE ASKED TO DO?

You will talk with a study coordinator to determine your eligibility. We are looking for men and women between 18 and 85 years of age and are former smokers with at least a 20 pack year history (packs per day x number of years smoked). The trial is open to both veterans and non-veterans.

You may first be asked to sign a screening consent in order to collect a sputum sample (coughed mucous). This would tell us if you have any abnormal cells (dysplasia). If you have mild, moderate, or severe dysplasia, you would be eligible. You would then read and sign a consent form that explains the study in detail. It also describes how clinical trial participants are protected during the study.

- We will perform a bronchoscopy before and after treatment. It is a procedure where your lungs will be looked at through a small tube/scope and small pieces of lung tissue (biopsies) will be collected and analyzed by a pathologist. You will receive the results of each bronchoscopy.
- You will be randomly assigned to take either the actual study drug inhaled iloprost or the placebo. The study is blinded so neither you nor the investigators will know which treatment you receive. You will use a nebulizer to inhale either a study drug (iloprost) or placebo for 2 months.
- At the start and near the end of the study we will ask permission to collect a sample of your blood and urine for this and future lung cancer studies.
- While you are on drug, we will conduct monthly tests to ensure you are tolerating the drug well: an office visit with the doctor, a blood draw to monitor your lab work, a 6 minute walk test, and a carbon monoxide breathing test.
- Other tests include: a pulmonary function test (breathing test) if you have not had a qualifying one in the past 6 months.

COMPENSATION AND COST

You can be paid up to $250 if you complete all study visits. There will be no cost to you for any study related test or visit.

HOW DO I LEARN MORE ABOUT PARTICIPATING IN THIS STUDY?

This study is voluntary and is not free of risks. Please call Brandi Bagwell at the University of Colorado Cancer Center at 303-724-1657. She will be glad to answer any questions you may have.
A PHASE I TRIAL OF INHALED ILOPROST FOR THE PREVENTION OF LUNG CANCER IN FORMER SMOKERS

COMIRB #14-1247

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