Clinical Research Trial for Hospitalized Patients with Influenza

Renee Stapleton, MD, PhD

Influenza infection is a major public health concern causing 250,000 to 500,000 worldwide deaths annually. Additionally, for those patients who are the most ill and are hospitalized, current available treatments, including oseltamivir (Tamiflu), do not seem to be very effective therapies. The National Institutes of Allergy and Infectious Disease (NIAID) has therefore funded a large randomized controlled trial of high-titer versus low-titer anti-influenza immune plasma in addition to standard care antivirals for the treatment of severe influenza A.

The Vermont Lung Center is excited to be a site for this study to offer our hospitalized adult patients with acute influenza A an opportunity to receive a novel and hopeful therapy. Up to 40 sites in the United States are participating. Across all sites, a total of 150 eligible patients will be randomized in a 2:1 ratio to receive either high-titer anti-influenza plasma or control (low-titer) plasma, which is given as a one-time dose. The plasma is collected from donors at 3 blood banks around the country and is tested for the level of antibodies to influenza A, then categorized as high, medium, and low/none. This study uses the high and low/none plasma. All study participants will undergo a series of tests and assessments during the study to determine if the treatment is working.

The primary endpoint of this study is participants' clinical status on study day 7 defined on a 6-point scale as follows: 1) death, 2) in ICU, 3) non-ICU hospitalization requiring supplemental oxygen, 4) non-ICU hospitalization not requiring supplemental oxygen, 5) not hospitalized but unable to resume normal activities, and 6) not hospitalized with full resumption of normal activities.
American Lung Association—Two Events!

Join the FORCE for Lung Health!

Every 5 minutes, someone in the U.S. is diagnosed with lung cancer, and more than 33 million Americans suffer from lung disease. Join the American Lung Association for two events to learn, share, care and raise funds to defeat lung cancer and other lung diseases.

LUNG FORCE Expo

Tuesday, May 9, 2017, Doubletree by Hilton, Burlington, Vermont

This special one-day education program brings together patients, caregivers and healthcare professionals with leading lung health experts to learn about cutting-edge treatments, medications, resources and research to fight lung cancer and lung disease. Cost: $20 for patients, $10 for caregivers, and $75 for healthcare professionals. Breakfast and lunch provided. The American Lung Association will provide full scholarships available for patients and caregivers in need. Register now at Action.Lung.org/BurlingtonExpo or call 802-876-6861 for more information.

LUNG FORCE Walk

Thursday, June 22, 2017, 5:00 - 7:30 p.m., Battery Park, Burlington, Vermont

A LUNG FORCE Walk is like no other charity event. With an inspiring signature song and music, we will celebrate the collective power of our breath. Our voices will soar as we rally our friends, neighbors and colleagues to stand together, and walk together, against lung cancer—and lung health for all. Register now at lungforce.org/walk or call 802-876-6860 for more information.
THE AMERICAN LUNG ASSOCIATIONS’ AIRWAYS CLINICAL RESEARCH CENTERS (ALA-ACRC) AIRWAYS PATIENT REGISTRY:

A registry of adults and children with a diagnosis of airways disease such as asthma and COPD especially specific subgroups (e.g. smokers, elderly, co-existing illnesses) to contact for active/upcoming studies and to develop future research protocols.

ASTHMA

- **Airway Compliance in Relation to BMI in Asthma** - Anne Dixon, MD

- **Effect of BMI on Allergic Airway Disease**
  Volunteers:
  Asthmatics—BMI greater than or equal to 35 who are enrolled in Bariatric Surgery Program / 1-10 visits / up to $1000
  Controls—BMI 18.5–24.9 who are undergoing routine scheduled abdominal surgery / 2 visits / $225 total

- **Increased Lung Volumes as Rescue Therapy**: - 5 Visits
- **Increased Lung Volumes as Controller Therapy**: - 3 Visits
  Volunteers: 18+ years / Compensation: $100 per visit - Anne Dixon, MD

IDIOPATHIC PULMONARY FIBROSIS (IPF) STUDIES

- **Idiopathic Pulmonary Fibrosis Prospective Outcomes (IPF-PRO) Registry** - Prema Menon, MD
  Volunteers: Ages 40+ newly diagnosed with IPF/a blood draw at regularly scheduled 6 month provider visits over 3-4 years

- **A Multicenter, Randomized, Double-Blinded, Placebo-Controlled Trial to Evaluate the Safety and Efficacy of Inhaled Treprostinil in Subjects with Pulmonary Hypertension Due to Interstitial Lung Disease Including Combined Pulmonary Fibrosis and Emphysema** - MaryEllen Antkowiak, MD
  Volunteers: 18 –79 years / diagnosed with Pulmonary Hypertension associated with interstitial lung disease including combined Pulmonary Fibrosis and Emphysema / 7 visits / up to $469

CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD)

- **Losartan Effects on Emphysema Progression - ALA/ACRC** - David Kaminsky, MD (Enrollment to begin soon)
  Randomized, Blinded Placebo-Controlled Multi-Site Clinical Trial of the Effects of Losartan on Progression of Emphysema.
  Volunteers: 40+ years old / current or former smoker greater than 10 Pack year history / 7 visits / Up to $425

- **IL-6 Receptor Production in COPD patients** - Mercedes Rincon, MD
  Volunteers: 18 – 85 years / 2 visits / Up to $150 for completing visit 2

- **The Effect of Lung Volume on Respiratory System Mechanics in Asthma and COPD** - David Kaminsky, MD
  Volunteers ages 18-60 years / Diagnosis of Asthma or COPD / 1 visit / $50

- **EMPROVE: A Prospective, Randomized, Controlled, Multicenter Clinical Study to Evaluate the Safety and Effectiveness of the IBV Valve System for the Single Lobe Treatment of Severe Emphysema** - Matthew Kinsey, MD
  Volunteers: Patients diagnosed with Severe Emphysema / for more information call Sara Ardren 802-656-7953

CYSTIC FIBROSIS

- **Novartis: A Prospective Observational Study in Cystic Fibrosis Patients With Chronic Respiratory Pseudomonas Aeruginosa Infection Treated with TOBI Podhaler (Tobramycin Inhalation Powder) or Other FDA Approved Inhaled Antipseudomonal Antibacterial Drugs** - Charlotte Teneback, MD
  Volunteers: 6+ years with CF who are using inhaled antibiotics / 1 study visit during a routine clinic visit and continued observation through five years.

- **STOP2: A Randomized, Controlled, Open-label Study Designed to Evaluate the Efficacy and Safety of Differing Durations of IV Treatment, Given in the Hospital or at Home for a Pulmonary Exacerbation in Adult Patients with CF** - Charlotte Teneback, MD
  Volunteers: 18+ years with CF and planning to start i.v. antibiotics to treat pulmonary exacerbation/ 3 visits / Up to $210

LUNG CANCER

- **Detection of Lung Heterogeneity as an Early Risk Factor for Lung Cancer in Patients Undergoing Lung Cancer Screening by Low Dose CT of the Chest** - David Kaminsky, MD
  Volunteers: Ages 15-79 yrs./ 30 pack year history of smoking / Currently smoking or have quit within 15 years, and have been referred for a Lung Cancer Screening /1 Visit / Compensation $100
Welcome: Ubong Peters Postdoctoral Associate at The University of Vermont

Ubong Peters is a Postdoctoral Associate working with Dr. Anne Dixon and Dr. Jason Bates.

For his Master’s and PhD thesis, Ubong helped develop a new device for measuring how difficult it is for patients to move air into and out of their lungs. Ubong’s thesis won 1st Place in the 2016 Dalhousie University 3-Minutes-Thesis Competition and 2nd Place in the 2016 Eastern Canada Regionals.

Ubong is a permanent resident of Canada and citizen of Nigeria. He was born and raised in Southern Nigeria, and he worked as a Graduate Assistant at Akwa Ibom State University (AKSU) after completing his Bachelor’s degree in Genetics/Biotechnology. In 2007, he was awarded the AKSU Staff Development Scholarship to undertake advanced studies and research in Biomedical Engineering at Dalhousie University in Halifax, Canada.

In his free time, Ubong enjoys traveling and listening to music.

**Be a Research Volunteer**

- The study will be explained via a consent for you to sign should you wish to be in the study.
- Studies may be therapeutic (involving observation of lung function). However, The Vermont Lung Center can make no claims that your involvement in a research study will improve your condition.
- Compensation may or may not be provided.

Call today: 802-847-2193