

Advertisement: A Randomized, Double-Blind, Placebo-Controlled, Multiple Dose Study of VX-809 to Evaluate Safety, Pharmacokinetics, and Pharmacodynamics of VX-809 in Cystic Fibrosis Subjects Homozygous for the DF508-*CFTR* Gene Mutation

This purpose of this research study is to learn more about the safety and effect that the study drug, VX-809 has on people with Cystic Fibrosis (CF) as compared to placebo. A placebo is a “sugar pill” which has no effect.

VX-809 is a study drug being tested to see if it improves the function and quantity of a protein called CFTR. Problems with CFTR in patients with CF lead to thick secretions in the lungs and other organs. This study will determine how the body absorbs and processes the study drug and determine drug dosing.

People 18 years of age and older with Cystic Fibrosis, who have a delta F508 *CFTR* mutation, may qualify to participate.

Your participation in this research study will last for about 60 days. The study drug will be a capsule taken once a day over a 28 day period. You will have physical exams including vital signs, blood and urine tests, sweat chloride tests, pulmonary function testing, nasal potential difference (NPD) tests, and EKG testing of your heart. You will answer questionnaires about your health and have 2 overnight stays in the hospital. You will be compensated for your time, travel and parking.

Principal Investigator: Michael Boyle, MD 410 955-1167

For more information, please contact:

Karen Callahan, RN, CCRP at 443-287-8983 or Carolyn Chapman, RN at 410-955-1167
Study number: NA_00025569