

WHAT IS COPD?

Chronic obstructive pulmonary disease (COPD) is a serious lung condition that makes it hard to breathe. In the early stages, smoke or other air pollutants damage the lungs, reducing their natural elasticity and causing inflammation. Over the years, these lung changes limit the amount of air that can go in and out of the lungs. Because of the lung damage and obstruction, many patients struggle to take a deep breath and can't get enough air.

WHAT IS A COPD FLARE-UP?

Many patients with COPD have occasional bad periods—usually lasting hours, days, or weeks—of worsening symptoms. These flare-ups of symptoms are called exacerbations.

The symptoms of an exacerbation include:

- more coughing or wheezing
- increased and thickened sputum (mucus or phlegm)
- intensified shortness of breath
- fever and respiratory infection

These exacerbations are not only extremely uncomfortable, but they can be life-threatening. Flare-ups often require a change in medication such as taking a corticosteroid pill, using oxygen therapy, or taking an antibiotic. In some cases, patients need to be hospitalized for a COPD exacerbation.

WHERE CAN I LEARN MORE ABOUT OR ENROLL IN STATCOPE ?

Log onto www.copdcrn.org or contact the COPD CRN site closest to you.

ALABAMA

University of Alabama at Birmingham
Birmingham, Alabama
205-996-6602, stidwell@uab.edu

Veteran's Administration Medical Center
Birmingham, Alabama
205-933-8101 ext 5550
janet.bowden@va.gov

CALIFORNIA

LA BioMed at Harbor-UCLA Medical Center
Los Angeles, California
310-222-8200, ldiaz@labiomed.org
310-222-8200, rkiledjian@labiomed.org

University of California at San Francisco
San Francisco, California
415-476-3259, rie.sakurai@ucsf.edu
415-476-5418, melanie.dyjak@ucsf.edu

COLORADO

University of Colorado
Aurora, Colorado
720-848-0757,
chris.verano@ucdenver.edu

National Jewish Health
Denver, Colorado
303-398-1518,
underwoodj@njhealth.org

MARYLAND

University of Maryland Baltimore
Baltimore, Maryland
410-706-3355,
tfitzger@medicine.umaryland.edu
wfarrell@medicine.umaryland.edu

MASSACHUSETTS

Brigham and Women's Hospital
Boston, Massachusetts
617-732-6272,
speterson2@partners.org

Veteran's Administration Medical Center
Boston, Massachusetts
617-323-7700 ext 36622,
kirby.matthess@va.gov

Fallon Clinic

Boston, Massachusetts
508-368-3929,
anne.mcdonald@fallon-clinic.org
kathleen.allain@fallon-clinic.org

MICHIGAN

University of Michigan
Ann Arbor, Michigan
734-764-7388, debthomp@umich.edu
734-763-6139, tinafelt@umich.edu

Veteran's Administration Medical Center
Ann Arbor, Michigan
734-845-3533, lmcclosk@umich.edu

MINNESOTA

Veteran's Administration Medical Center
Minneapolis, Minnesota
612-467-5519, angela.fabbrini@va.gov
612-467-5203, doris.stuber@va.gov

HealthPartners Research Foundation
Minneapolis, Minnesota
952-967-7862,
linda.m.loes@healthpartners.com
952-967-5056,
pamela.j.neuenfeldt@healthpartners.com

Mayo Clinic
Rochester, Minnesota
507-284-9259,
bornhorst.cathy@mayo.edu
507-284-9946,
andrist.boleyn@mayo.edu

PENNSYLVANIA

Temple University Lung Center
Philadelphia, Pennsylvania
215-707-4260,
dolores.fehrel@tuhs.temple.edu
215-707-9611,
heidi.smith@tuhs.temple.edu

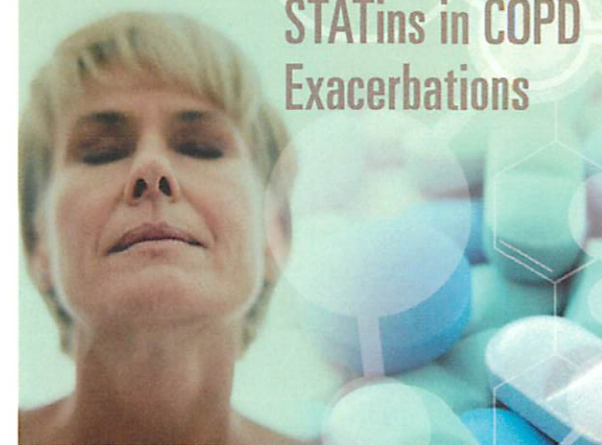
Pittsburgh VA Medical Center
Pittsburgh, Pennsylvania
412-360-1527,
kathryn.hartwig@upmc.edu

University of Pittsburgh
Pittsburgh, Pennsylvania
412-802-8623, knioekll@upmc.edu

HAVE YOU HAD COPD FLARE-UPS? TAKING A STATIN PILL ONCE-A-DAY MAY HELP.

STATCOPE

STATins in COPD Exacerbations



The National Heart Lung Blood Institute (NHLBI) COPD Clinical Research Network (CCRN) and its nationwide network of clinical sites are conducting a trial to find out if a statin—currently used to help patients reduce cholesterol and prevent heart disease—can help reduce flare-ups in patients with COPD.



STATCOPE is coordinated by the COPD CCRN, a consortium of research centers that receives funding from the National Heart, Lung, and Blood Institute (part of the U.S. National Institutes of Health).

HOW WILL STATCOPE HELP DISCOVER NEW TREATMENT FOR FLARE-UPS?

Lung inflammation increases during COPD flare-ups. Statin medications are known to decrease inflammation throughout the body. Also, some research shows that people with COPD who were given statins for high cholesterol had fewer respiratory symptoms.

This trial is designed to determine if statins can reduce the number and severity of COPD exacerbations in patients who are at risk of these flare-ups.

STATCOPE is important because although statins are already used by millions of people with heart disease, they do have side effects. This trial will carefully weigh the benefits and risks of a once-a-day dose of statin in a three-year study of over 1,000 COPD patients.

STATCOPE will help doctors decide if this type of medication might help the millions of COPD patients who are prone to flare-ups.

WHO IS ELIGIBLE TO PARTICIPATE?

To be part of this trial you must:

- Have moderate or severe COPD
- Have a recent history of flare-ups
- Be 40 to 80 years of age
- Be a current or ex-smoker
- Not have active heart disease or high cholesterol
- Not be taking statins

HOW DOES STATCOPE WORK?

Potential participants will be screened for eligibility by one of the clinical sites around the country. If you are eligible for the trial, you may receive study medication or a placebo (an inactive substance) and medical tests, including breathing and blood tests, at no cost during the trial. You will be asked to answer questions about your medical history and symptoms. You will be eligible for some compensation for the costs associated with your participation in the trial.

- All participants will be randomly assigned to 1 of 2 groups:
 - 1) those who take a pill that contains simvastatin
 - 2) those who take a placebo pill (an inactive substance)
- You will take your pill, once per day for 1 to 3 years.
- You will be taught about the potential side effects of the study medication.
- You will continue to use your usual COPD treatments.
- You will need to come back to the clinic where you enrolled about 2 to 4 times per year for blood tests and exams.
- You will need to answer a phone survey about 6 to 7 times per year.
- If you have a flare-up, you will go to see your own doctor or hospital as usual and you will inform them that you are in the trial. You will call the clinical site later to tell them about the medical care that you received for treating the flare-up.

WHY SHOULD I CONSIDER PARTICIPATING IN STATCOPE?

- You will receive tests and advice from lung experts.
- You will get new ideas and support to deal with COPD.
- You will help answer an important question about the value of statins in reducing the risk of COPD flare-ups.
- You will gain a personal satisfaction knowing that your result could help others who have COPD.

