

# OHIOHEALTH

## CONSENT FORM

**TITLE OF STUDY: NEBULIZED HYPERTONIC SALINE FOR INPATIENT USE IN CHRONIC OBSTRUCTIVE PULMONARY DISEASE**

**PRINCIPAL INVESTIGATOR: KRUTI PATEL, D.O.**

We are conducting a clinical trial (a type of research study). Clinical trials include only patients who choose to take part in the study. This consent form serves two purposes. First, it provides information on the procedures and risks involved in the clinical trial, so that you can decide if you want to take part in the study.

Second, this form will ask for your permission to use and release the medical information that we will get from you during this study. Please take your time to make your decision about taking part. You may discuss your decision with your friends and family. If you have any questions, you can ask your study doctor for more explanation.

This study is being sponsored by Doctors Hospital Research and Education Office.

You are being asked to take part in this study because you were admitted to Doctors Hospital with chronic obstructive pulmonary disease (COPD).

### **WHY IS THIS STUDY BEING DONE?**

The purpose of this study is to see if there is a difference between two different types of saline (salt water), mixed with albuterol, a COPD treatment, in regards to improvements in a breathing test (Modified Borg Dyspnea Scale).

### **WHAT IS INVESTIGATIONAL ABOUT THIS STUDY?**

We would like to see if there is any difference between patients who receive standard saline and hypertonic saline in regards to improvements in their COPD symptoms.

### **HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?**

About 146 people will take part in this study locally through Doctors Hospital.

## **WHAT WILL HAPPEN IN THE STUDY?**

You will be “randomized” into one of the study groups described below. Randomization means that you are put into a group by chance. It is like flipping a coin. A computer will decide which group you are in. Neither you nor the study doctor will choose what group you will be in. You will have an equal chance of being placed in either group.

Once you have agreed to participate in the study, you will be placed in one of the following groups.

Group 1 will receive 2.5 mg albuterol with standard 0.9% saline

Group 2 will receive 2.5 mg albuterol with nebulized 3% saline

Prior to receiving your treatment, you will be given the Modified Borg Dyspnea Scale to assess the severity of your symptoms prior to your treatment. You will then receive albuterol treatments every six hours for 24 hours. After the 24 hour period, we will assess your symptoms once again.

## **HOW LONG WILL I BE IN THE STUDY?**

You will be in the study until you are discharged from the hospital.

You can stop being a part of this study at any time. However, if you decide to stop being in the study, please talk to the study doctor first.

## **WHAT ARE THE RISKS OF THE STUDY?**

While on the study, you are at risk for the following side effects. You should discuss these with the study doctor. We will be looking at your medical records up to 30 days after you leave the hospital to see if you need to return.

### **Risks and side effects related to nebulized saline include:**

Common:

- Cough, wheeze, shortness of breath due to muscle tightening in the lungs (bronchospasm)
- Sore throat

Uncommon, but serious:

- Fluid in the lungs (pulmonary edema)
- Chest pain

**Risks and side effects related to albuterol include:**

Common:

- Fast heart rate (tachyarrhythmia)
- Low potassium levels
- Sore throat/irritation
- Shaking (tremors)

Uncommon, but serious:

- Upper respiratory tract infection
- Sinus infection (rhinitis)
- Abnormal heart rhythm (atrial fibrillation)
- Heart attack
- Water in the lungs (pulmonary edema)

Rare:

- Rapid heart rhythm (supraventricular tachycardia)
- Itching
- Swelling of the mouth, face, lips, and throat (angioedema)
- Rash
- Muscle tightening in the lungs (bronchospasm)
- Dizziness
- Nervousness
- Headache
- Sleeplessness
- Nausea, stomach upset
- Nasal congestion
- Throat irritation (pharyngitis)
- High blood pressure
- Cough

There also may be other side effects that we cannot predict. Many of these side effects are often manageable and reversible. You will be observed for side effects and all medically appropriate efforts will be made to prevent and/or control them. If there are side effects that cannot be controlled or reversed, they may result in serious injury or death.

**YOU SHOULD REPORT ANY OF THESE PROBLEMS TO THE STUDY DOCTOR IMMEDIATELY SO THAT APPROPRIATE CARE CAN BE GIVEN. SIDE EFFECTS OTHER THAN THOSE LISTED HERE MAY ALSO OCCUR. TALK TO THE STUDY DOCTOR ABOUT ANY SIDE EFFECT THAT SEEMS UNUSUAL OR THAT IS ESPECIALLY BOTHERSOME TO YOU.**

## **ARE THERE BENEFITS TO TAKING PART IN THE STUDY?**

If you agree to take part in this study, there may or may not be direct medical benefit to you. While doctors hope that treatment with hypertonic saline will be more beneficial, as compared to standard saline, there is no proof of this. We do know that the information from this study will help doctors learn more about the use of hypertonic saline as a treatment for COPD symptoms. This information could help future patients with your condition.

## **WHAT OTHER OPTIONS ARE THERE?**

Since you will be receiving albuterol treatments for your COPD, you will most likely receive the standard 0.9% saline.

Please talk to your doctor about these and other options.

## **WHAT ARE THE COSTS?**

Taking part in this study will not lead to added costs to you or your insurance company. The nebulized saline will be provided free of charge. Non-routine costs required by the study will be paid by the sponsor.

While you are in this study, you may receive tests, procedures, and exams that are standard medical care. This standard medical care may or may not be covered by your medical insurance.

If your medical insurance does not pay for this standard medical care, you will be responsible for the cost of medical care related to your condition, including but not limited to tests, deductibles, co-payments, study doctor and clinic fees, hospitalization and procedures.

## **WHAT IF AN INJURY OCCURS BECAUSE OF THE STUDY TREATMENT?**

In the case of injury or illness resulting from this study, emergency medical treatment is available but will be provided at the usual charge. No funds have been set aside to compensate you in the event of injury or illness. You or your insurance company will be charged for continuing medical care and/or hospitalization.

## **COMPENSATION?**

You will receive no payment for taking part in this study.

## **WHAT INFORMATION WILL BE COLLECTED FROM ME FOR USE IN THE STUDY?**

The medical information that will be collected from you if you take part in this study includes:

- Information obtained from procedures used to determine your eligibility to take part in the research study, including a routine medical history, physical exam, and spirometry data (breathing test).
- Information that is created or collected from you during your participation in the study, including your over-all medical condition, albuterol use, results of the Modified Borg Dyspnea Scale, and follow-up information up to 30 days.
- Information contained in your underlying medical records related to your medical history and treatment prior to this study

The above information may identify you by name, address, telephone number, social security number, health plan number, study number, date of birth, dates relating to various medical procedures, or other identifying information.

## **WHAT ABOUT CONFIDENTIALITY?**

If you sign this form and take part in this study, the study staff will be authorized to use the information described above to carry out the purposes of the research study. The study staff will also be authorized to disclose the information described above to all of the following parties involved in the research study:

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as:

- OhioHealth Institutional Review Board # 2
- Doctors Hospital Research and Education Office
- The U.S. Food and Drug Administration (FDA) and other government agencies.
- The Department of Health and Human Services Office of Human Subject Research Protections
- The Centers for Medicare and Medicaid Services (CMS)
- The financial agent for CMS
- OhioHealth Research and Innovation Institute Office of Regulatory Compliance

Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. Once your information is disclosed to the study sponsors, the IRB or the government agencies described above, there is a potential that your medical

information will be re-disclosed and will no longer be protected by federal privacy regulations.

Your study number and initials will be used rather than your name as an identifier on your study records.

If we publish the information we learn from this study in a medical journal, you will not be identified by name or in any other way.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

### **DO I HAVE THE RIGHT TO DECLINE AUTHORIZATION?**

You have the right to decline to sign this authorization to use/disclose your medical information. If you decline, you will not be able to take part in this research study. Except as described herein, if you decline to sign this authorization, your rights concerning treatment, payment for services, enrollment in a health plan or eligibility for benefits will not be affected.

### **HOW LONG WILL MY AUTHORIZATION REMAIN IN EFFECT?**

The authorization for use and disclosure of your information will remain in effect until the study is complete.

### **CAN I WITHDRAW MY AUTHORIZATION?**

You may withdraw your authorization at any time by sending a written request to the Principal Investigator at:

Kruti Patel, D.O.  
Doctors Hospital Research and Education Office  
5100 W. Broad St.  
Columbus, Ohio 43228

If you withdraw your authorization:

- Your participation in the study will end
- The study staff will stop collecting your medical information

Your medical information that has already been used and disclosed prior to withdrawing your authorization remains a part of the research study data.

While the research study is in progress, your access to your study records will be temporarily suspended. Afterwards, you have the right to see and copy the medical information collected from you in the course of the study, for as long as that information is maintained by the study staff and other entities subject to federal privacy regulations.

## **WHAT ARE MY RIGHTS AS A PARTICIPANT?**

Your doctor has answered your questions. You can ask your doctor questions at any time.

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to which you are entitled.

We will tell you about important new information that may affect your health, welfare and willingness to stay in this study.

## **WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?**

For questions about the study or a research-related injury, contact the study doctor, Kruti Patel, DO, at 614-857-7735.

For questions about your rights as a research participant, contact Dr. Randall Franz, Chairman of the OhioHealth Institutional Review Board # 2, which is a group of people who review the research to protect your rights at (614) 566-4431 for Dr. Franz or Customer Service at (614) 566-5708.





IF THE PATIENT IS PARTICIPATING BUT UNABLE TO GIVE CONSENT,  
INDICATE WHY.

---

---

\_\_\_\_\_  
Witness to consent process  
(if applicable)

\_\_\_\_\_  
Date

\_\_\_\_\_  
Time