Determining Optimal Dose of Corticosteroids in COPD Exacerbations: A Pilot Study

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RUTGERS
Robert Wood Johnson
Medical School

Department of Medicine
Division of General Internal Medicine

I. SUBJECT CONSENT TO TAKE PART IN A RESEARCH STUDY

TITLE OF STUDY: Determining Optimal Dose of Corticosteroids in COPD Exacerbations: A Pilot Study
Principal Investigator: Jeffrey L. Carson, MD

This consent form is part of an informed consent process for a research study and it will provide information that will help you to decide whether you wish to volunteer for this research study. It will help you to understand what the study is about and what will happen in the course of the Study.

If you have questions at any time during the research study, you should feel free to ask them and should expect to be given answers that you completely understand.

After all of your questions have been answered, if you still wish to take part in the study, you will be asked to sign this informed consent form.

You are not giving up any of your legal rights by volunteering for this research study or by signing this consent form.

Who is conducting this research study?

Dr. Carson is the Principal Investigator of this research study. A Principal Investigator has the overall responsibility for the conduct of the study. However, there are often other individuals who are part of the research team.

Dr. Carson may be reached at:

Rutgers-Robert Wood Johnson Medical School
Division of General Internal Medicine
125 Paterson Street – 2nd Floor
New Brunswick, NJ 08901
732-235-7122

The principal investigator or another member of the study team will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep.

Why is this study being done?

COPD (chronic obstructive pulmonary disease) is a long-lasting lung disease usually caused by long-term smoking. COPD can get worse (called an exacerbation), making people sick enough to need hospitalization. Increased shortness of breath, a worsening cough, or coughing up larger quantities of mucus are all signs of an exacerbation. Corticosteroids are the medicines that doctors use to treat COPD. They are very effective and are always used, but nobody knows the right dose. Higher doses may work better but could cause more side effects than lower doses. Typical treatment is for 7 to 10 days, starting with a beginning dose which is then decreased over the treatment days. This study will compare a higher dose corticosteroid regimen with a lower dose corticosteroid regimen. It is unknown which treatment works better.

Why have you been asked to take part in this study?

You are being invited to take part in this study because you have been diagnosed by an emergency room physician or your doctor to have a COPD exacerbation, which requires treating you with corticosteroids. You have also met our eligibility criteria, and your doctor has agreed to follow our study protocol. A study staff member was contacted to inform you of our study and to ask for your consent.

Who may take part in this study? And who may not?

To take part in this study you must:

1. Be more than 40 years old.
2. Have smoked at least 10 pack-years (calculated by multiplying your packs-per-day by how many years you have smoked)
3. Have a diagnosis of COPD or a related disease such as emphysema or chronic bronchitis.
4. Have come to the emergency room with increased shortness of breath, mucus production, or cough and your doctor wants you to stay in the hospital.

You may NOT take part in this study:

1. If you have a different medical problem to explain your symptoms
2. If you are so ill that you currently require a breathing tube to breathe comfortably.
3. If you are pregnant, if there is a possibility that you may be pregnant, or if you are currently breast-feeding.
4. If you are a woman of child-bearing age and you cannot use one of the birth control methods indicated below.

How long will the study take and how many subjects will participate?

There will be up to 125 patients enrolled in this study. Each patient will be followed for 30 days. It will take about 2 years to complete the study.

What will you be asked to do if you take part in this research study?

The initial dose of corticosteroids that you receive will be set by random rules of research (like a coin flip) to either lower dose or higher dose. This daily dose will be gradually decreased over the course of 10 days. If you are discharged from the hospital before your treatment is completed, you will be given the remainder to take at home. The medicine may be administered orally (a pill) or through a vein (an IV). Your doctor will decide which way is best for you. Neither you nor your doctor will know which dose you are receiving. Your doctor will always be able to change the dose of medicine you are receiving if he feels it in your best interest. Your medical record will be reviewed at the end of your hospitalization. Study staff will contact you by telephone at 30 days after you enter to the study to see how you are doing and to find out if you have had any additional hospitalizations. We will ask you a few questions about your COPD symptoms. It will take about 2 minutes to answer these questions.

We will also have you sign a form that gives the study staff permission to receive the medical records from any hospitalization or doctors' office visits that you have within the next 30 days. If you do not agree to sign the release of records form, you cannot participate in the study.

What are the risks and/or discomforts you might experience if you take part in this study?

Corticosteroids are necessary and are given routinely in the treatment of COPD exacerbations. There is a range of doses used to treat COPD.. We are evaluating the effects of the drug at 2 different doses within this range. Important side effects from corticosteroids include high blood sugar, infection, stomach bleeding, hormonal changes, and changes in mood. These side effects improve once the medication is stopped.

Even while on corticosteroids, your COPD exacerbation may be complicated by worsening symptoms, need for a breathing tube, and even death in the most severe circumstances.
You should not take any over-the-counter medicines, herbal products, vitamins or food supplements while taking part in this study, unless you tell the study doctor and get permission from the study doctor to go on taking these medicines. You will follow the instructions of the study doctor about the use of any of these products.

You should also tell the study doctor about all medicines that other doctors may have prescribed for you to take.

Corticosteroids are known to cause menstrual irregularity. They are also known to rarely cause birth defects in pregnant women. If you are a woman of childbearing age and you are sexually active, you are required to use one of the following methods of contraception while taking the study drug: condoms, female condoms, cervical caps, diaphragms, and IUDs (intrauterine device). If you are unwilling to use one of these birth control measures, you cannot participate in this study. You should be aware that corticosteroids decrease the effectiveness of hormonal birth control (pills, injections) and that you should not rely on hormonal birth control while on corticosteroids.

Are there any benefits for you if you choose to take part in this research study?

There is no direct benefit from taking part in this study. The results of this study may help doctors in deciding the best dose of corticosteroids for future patients.

What are your alternatives if you don't want to take part in this study?

Your doctor plans to treat you with corticosteroids even if you do not take part in this study. There are multiple therapies that are available for COPD exacerbation in addition to corticosteroids. Participation in this study does not exclude you from receiving other therapy. Corticosteroids are already a standard part of therapy for COPD exacerbation. In addition, if your condition necessitates a change of corticosteroid dosage, this will still be possible under your doctor's supervision.

How will you know if new information is learned that may affect whether you are willing to stay in this research study?

If new information is learned that may affect you during or after the study, you will be contacted.

Will there be any cost to you to take part in this study?

You will not incur any additional cost from taking part in this study, though you will still be responsible for the cost of any additional medications you normally take. The study drug will be provided free of cost to subjects enrolled in this study. Please contact your health plan for further information.

Will you be paid to take part in this study?

You will not be paid for your participation in this research study.

What kind of information will be collected about me?

Your comprehensive medical chart will be reviewed (including physician's documentation, lab work, and radiology studies). Hospital records will be obtained from your current admission, prior admissions, as well as any repeat admissions (even to other hospitals) within 30 days of your hospitalization. Your primary physician will also be contacted regarding how well you recovered from your COPD flare, and comprehensive records will be obtained from your physician's office.

How will information about you be kept private or confidential?

All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed. The data obtained from reviewing your medical chart, in addition to any telephone or paper survey information, will be kept at a secure location. Your name and other personal identifiers will be removed from the research files after data collection is complete and prior to analysis.

A description of this clinical trial will be available on 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 website at any time.

What will happen if you are injured during this study?

Corticosteroids do have known risks of physical injury. It is possible that during the course of these studies, new adverse effects of corticosteroids that result in physical injury may be discovered. Medical and/or dental treatment will be arranged by Rutgers for participants who sustain physical injuries or illnesses as a direct consequence of participation in this research. Your insurance carrier or other third party payer will be billed for the cost of this treatment. However, your health insurance company may or may not pay for treatment of injuries as a result of participation in this study. No additional financial payment to you is available.

What will happen if you do not wish to take part in the study or if you later decide not to stay in the study?

Participation in this study is voluntary. You may choose not to participate or you may change your mind at any time.

If you do not want to enter the study or decide to stop participating, your relationship with the study staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.

You may also withdraw your consent for the use of data already collected about you, but you must do this in writing to Dr. Jeffrey Carson (Clinical Academic Building, 125 Paterson St., Suite 2300, New Brunswick, NJ 08901-1962).

Beginning on the date that you withdraw your approval, no new personal health information will be used for research. However, the study doctor/investigator may continue to use the health information that was provided before you withdrew your approval.

At any time, the study doctor can take you out of this study because it would not be in your best interest to stay in it. Your study doctor can stop treatment even if you are willing to stay in the study.

If you decide to withdraw from the study for any reason, you may be asked to return for at least one additional visit for safety reasons.

Who can you call if you have any questions?

If you have any questions about taking part in this study or if you feel you may have suffered a research related injury, you can contact the study doctor:

Jeffrey Carson, M.D.
Clinical Academic Building
125 Paterson St., Suite 2300
New Brunswick, NJ 08901-1962
732-235-7122

If you have any questions about your rights as a research subject, you can call:

IRB Director
(732)-235-9806

And

Human Subject Protection Program
(732)-235-8578

What are your rights if you decide to take part in this research study?

You have the right to ask questions about any part of the study at any time. You should not sign this form unless you have had a chance to ask questions and have been given answers to all of your questions.

PERMISSION (Authorization) TO USE OR SHARE HEALTH INFORMATION THAT IDENTIFIES YOU FOR A RESEARCH STUDY

Information about you and your health is personal and private, so this information generally cannot be used in research without your written permission. The next few paragraphs tell you about how researchers want to use and share your health information in this research study. Your information will only be used as described here or as allowed or required by law. Ask questions if you do not understand any part of the research or the use of your health information. If you sign this consent form, you agree to let the researchers use your information in the research and share it with others as described below.

What is the purpose of the research and how will my information be used?

You are being invited to take part in this research study which is described at the beginning of this form. The purpose of collecting and using your health information for this study is to help researchers answer the questions that are being asked in the research.

What information about me will be used?

Your health information related to this study, may be used or disclosed in connection with this research study, including, but not limited to: all the information in your medical record (including lab tests, radiologic studies, physician's notes, histories, and physical examinations), telephone and paper surveys.

Who may use, share or receive my information?

The research team may use or share your information (but not your identity) collected or created for this study with the following people and institutions:

- The Rutgers-Institutional Review Board
- Principal Investigator
- Research Team (Including the Steering Committee, Study Coordinators, and Study Statisticians)

Those persons or organizations that receive your information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, if permitted by the laws governing them.

Will I be able to review my research record while the research is ongoing?

No. We are not able to share information in the research records with you until the study is over. To ask for this information, please contact the Principal Investigator, the person in charge of this research study.

Do I have to give my permission?

No. You do not have to permit use of your information. But, if you do not give permission, you cannot take part in this research study. (Saying no does not stop you from getting medical care or other benefits you are eligible for outside of this study.)

If I say yes now, can I change my mind and take away my permission later?

Yes. You may change your mind and not allow the continued use of your information (and to stop taking part in the study) at any time. If you take away permission, your information will no longer be used or shared in the study, but we will not be able to take back information that has already been used or shared with others. If you say yes now but change your mind later for use of your information in the research, you must write to the researcher and tell him or her of your decision:

Dr. Jeffrey L Carson
Rutgers-Robert Wood Johnson Medical School
Division of General Internal Medicine
125 Paterson Street – 2nd Floor
New Brunswick, NJ 08901

How long will my permission last?

There is no set date when your permission will end. Your health information may be studied for many years.

AGREEMENT TO PARTICIPATE

1. Subject consent:

I have read this entire form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form or this study have been answered. I agree to take part in this research study.

Subject Name:_____

Subject Signature:_____ Date:_____

2. Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed the full contents of the study including all of the information contained in this consent form. All questions of the research subject and those of his/her parent or legally authorized representative have been accurately answered.

Investigator/Person Obtaining Consent (printed name):_____

Signature:_____ Date: _____