

**Northwestern University
Department of Orthopaedic Surgery**

Consent Form and HIPAA Authorization for Research

PROTOCOL TITLE: A single blind, prospective, randomized controlled trial on the effect of local steroid application versus intravenous steroids on dysphagia following anterior cervical discectomy and fusion (ACDF)

PRINCIPAL INVESTIGATOR: Alpesh A. Patel, MD, FACS

SUPPORTED BY: Northwestern University (NU)

Introduction

You are being asked to take part in a research study. This document has important information about the reason for the study, what you will do if you choose to be in this research study, and the way we would like to use information about you and your health.

Conflict of Interest Disclosure

The following disclosure is made to give you an opportunity to decide if this relationship will affect your willingness to participate in this research study:

Your doctor, who is also the person responsible for this research study, is interested in both your clinical care and the conduct of this research study. You have the right to discuss this study with another person who is not part of the research team before making your decision whether or not to be in the study.

What is the reason for doing this study?

You are being asked to participate because you are undergoing anterior cervical dissection and fusion (ACDF) and therefore may experience the common side effects of dysphagia (difficulty swallowing) and dysphonia (voice changes).

Previous studies have shown that administering steroids after surgery often relieve these symptoms. Through this study we would like to assess what method of administering these steroids is the most effective, i.e. intravenous compared to local application.

How many people will take part in this study?

The study investigators hope to enroll 85 subjects at NU.

What will you do if you choose to be in this study?

If you consent to participate, you will be randomized to one of the following groups: group I (Control group), group II (Intravenous Decadron), or group III (Triamcinolone on gel foam sponge dabbed on the cervical plate). Randomization means you will be randomly assigned to a treatment based on chance, like a flip of a coin. Neither you nor the researcher chooses your assigned group. You will have an equal chance of being in either group.

Additionally, we will also request you to fill out questionnaires about your swallowing, voice, general health, and quality of life. These questionnaires are called: 1. The Eating Assessment Tool (EAT-10) questionnaire, 2. The Voice Handicap Index (VHI-10) questionnaire, 3. The Neck Disability Index (NDI) questionnaire, 4. The VAS Pain score questionnaire, 5. The Bazaz score questionnaire, and the 6. EuroQol EQ-5D questionnaire. You will complete these questionnaires prior to surgery, as well as 1 day, 2 weeks, 6 weeks, 3 months, 6 months, and 1 year after surgery. These questionnaires will take approximately one hour to complete. These questionnaires will be administered in the hospital, during your post-operative clinic visits with your surgeon, or over the phone.

What are some of the possible risks and discomforts?

A potential risk related to your participation in this study is the loss of privacy. To reduce these risks, all of the information collected will be recorded by number, not by name and stored securely. Additionally, some of the questions asked may be upsetting, or you may feel uncomfortable answering them. If you do not wish to answer a question, you may skip it and go to the next question.

There is also a physical risk from this study. The use of steroids may have an adverse effect on wound healing and/or transiently elevate blood sugar. However, in order to minimize this risk, we will only enroll patients that do not have diabetes or other endocrine disorders in this study.

What are the Possible Benefits for Me or Others?

You are not likely to have any direct benefit from being in this research study. However, your participation in the study will help orthopaedic surgeons better understand how to treat dysphagia and dysphonia after ACDF surgery.

What other procedures or courses of treatment might be available to me?

You do not have to take part in this research study. You can still have the procedure regardless of whether you consent to participate in the study. If you do not take part in this study, the care or treatment you receive at this hospital or any other hospital will not be affected.

Are there any financial costs to being in this study?

There will be no costs to you for being in this study.

The cost of your conventional medical care will be billed to you or to your health insurance company in the usual way. However, some health insurance plans will not pay the costs for people taking part in studies. Check with your health plan or insurance company to find out what they will pay for. Taking part in this study may or may not cost your insurance company more than the cost of getting regular treatment. If your insurance does not pay, you will be responsible for the charges of your conventional medical care.

Will I receive payment for participation in this study?

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

What should I do if I am injured as a result of being in this study?

If you become ill or get an injury or illness as a result of study (medications, devices or procedures), you should seek medical treatment through your doctor or treatment center of choice. You should promptly tell the study doctor about any illness or injury.

The hospital [university, researchers] will not pay for medical care required because of a bad outcome resulting from your participation in this research study. This does not keep you from seeking to be paid back for care required because of a bad outcome.

If I have questions or concerns about this research study, whom can I call?

You can call us with your questions or concerns.

If you have any illness or injury during your time on this study, you should call us promptly.

Dr. Alpesh A. Patel, MD is the person in charge of this research study. You can call him at 312-695-5902 during Monday through Friday, 9am to 5pm.

You can also call Dr. Rueben Nair, MD with questions about this research study. You can call him at 734-644-6285 during Monday through Friday, 9am to 5pm.

For problems arising evenings or weekends, you may call Dr. Rueben Nair, MD at (734) 644-6285.

If you are unable to reach Drs. Patel or Nair, you may call Surabhi Bhatt at 312-472-6024 during Monday through Friday, 9am to 5pm.

What are my rights as a research subject?

If you choose to be in this study, you have the right to be treated with respect, including respect for your decision whether or not you wish to continue or stop being in the study. You are free to choose to stop being in the study at any time.

Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. Specifically, your choice not to be in this study will not negatively affect your right to any present or future medical treatment.

Any new findings developed during the course of this research that may affect your willingness to continue in this study will be shared with you.

If you want to speak with someone who is not directly involved in this research, or have questions about your rights as a research subject, please contact the Northwestern University Institutional Review Board (IRB) Office. You can call them at 312-503-9338.

What about my confidentiality and privacy rights?

We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that includes health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. Your health information we may collect and use for this research includes:

- All information in a medical record
- Results of physical examinations
- Medical history
- Lab tests, or certain health information indicating or relating to a particular condition as well as questionnaires

- Records about study medication or drugs

During this study you may be coming to the Northwestern Medicine (NMG) clinical offices for research appointments or to get clinical services, such as lab tests, needed for the study. When that happens, you will be scheduled for these services through the NMG computer system. When a clinical exam or lab is done by NMG or one of its employees for the purpose of this research study, that information will be kept in both NMGs clinical records and in the study records.

The following groups of people may give the researchers information about you:

- All current and previous health care providers, including but not limited to the Northwestern Medicine Group (NMG) Northwestern Memorial Hospital (NMH).

Once we have the health information listed above, we may share some of this information with the following people. Please note that any research information shared with people outside of Northwestern University and its clinical partners (or affiliates) will not contain your name, address, telephone or social security number or any other direct personal identifier unless disclosure of the direct identifier is required by law [except that such information may be viewed by the Study sponsor and its partners or contractors at the Principal Investigators office]

- Authorized members of the Northwestern University workforce, who may need to see your information, such as administrative staff members from the Office for Research, Office for Research Integrity and members of the Institutional Review Board (a committee which is responsible for the ethical oversight of the study),
- Clinical affiliates, including but not limited the Rehabilitation Institute of Chicago (RIC), Northwestern Memorial Hospital (NMH), and the Ann & Robert H. Lurie Children's Hospital of Chicago (Lurie Children's). Your participation in this clinical trial will be tracked in an electronic database and may be seen by investigators running other trials that you are enrolled in and by your healthcare providers.
- Study monitors and auditors who make sure that the study is being done properly,
- Government agencies and public health authorities, such as the Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS).

Those persons who get your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission.

The results of this study may also be used for teaching, publications, or presentations at scientific meetings.

Please note that:

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- You do not have to sign this consent form. If you do not, it will not affect your treatment by health care providers, or the payment or enrollment in any health plans, or affect your eligibility for benefits. However, you will not be allowed to take part in this research study.
- You may change your mind and “take back” (revoke) this consent at any time. Even if you revoke this consent, the Principal Investigator may still use or share health information that was obtained about you before you revoked your consent as needed for the purpose of this study. To revoke your consent for the use of your health information, you must do so in writing to:

Dr. Alpesh A. Patel, MD, FACS

Department of Orthopaedic Surgery

676 N. St. Clair, Suite 1350

Chicago, IL 60611

- Unless you revoke your consent, it will not expire.

Consent Summary:

I have read this consent form and the research study has been explained to me. I have been given time to ask questions, and have been told whom to contact if I have more questions. I agree to be in the research study described above. A copy of the consent form will be provided to me after I sign it.

A copy of this signed consent document, information about this study and the results of any test or procedure done may be included in my medical record and may be seen by my insurance company.

Subject's Name (printed) and Signature

Date

Name (printed) and Signature of Person Obtaining Consent

Date