

HOSPITAL FOR SPECIAL SURGERY

535 East 70th Street
New York, NY 10021

INFORMED CONSENT TO PARTICIPATE IN RESEARCH

TITLE: Do Intraoperative Topical Corticosteroids Aid in the Prevention of Postoperative Dysphagia Following Elective Anterior Cervical Discectomy and Fusion? A Randomized, Controlled, Double Blinded Clinical Trial

PROTOCOL NO.:

SPONSOR: **Not Applicable**

INVESTIGATOR: **Todd J. Albert, MD**

SITE(S): **Hospital for Special Surgery, New York, NY**

STUDY-RELATED PHONE NUMBER(S): **(212) 774-7183**

IRB #: **2014-145**

You are being asked to take part in a research study conducted by Hospital for Special Surgery (HSS). You are being asked to participate in this study because you are undergoing spine fusion surgery on your neck.

You will still be responsible for the cost of your medical care just as you would be if you were not part of this study. For example, any co-pays, deductibles, and co-insurance associated with your medical care.

This document provides you with information about this study. After reading this document, any questions you may have will be answered. You may take home a copy of this document to consider or discuss with family and friends before making your decision.

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.

1. WHY IS THIS STUDY BEING DONE?

You have been asked to participate in this research study because you are scheduled to have spine surgery on the front of your neck. One of the known complications after spine surgery from the front of the neck is difficulty or painful swallowing. This complication can result from

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soft tissue swelling in front of the bones that make up the spine in your neck. The research study involves the application of topical steroids directly in the surgical site. Topical steroids are known to reduce swelling where they are applied. The purpose of this study is to determine if topical steroids can decrease the risk of swallowing difficulties after the type of neck surgery you will undergo. Steroids are being used “off-label” for this study. While steroids are approved for a variety of uses by the Food and Drug Administration, but because they have not been studied in this type of procedure, this is what is known as “off label” use. It is important to understand that the study does not change your neck surgery. The study only involves the application of topical steroids during your surgery if you are selected to receive it.

Your overall participation will continue over the course of 12 months.

The surgical procedure, imaging studies, and doctor visits you will have are exactly the same whether or not you participate in this study with the exception of:

- 1) Whether you receive topical steroids during your neck surgery will be randomized (like a flip of a coin).
- 2) You will be asked to complete the following questionnaires:
 - a. how swallowing problems have been affecting your quality of life
 - b. how often you are experiencing problems consuming liquids and solids
 - c. how much neck pain you have and how neck related pain affects your quality of life

2. WHAT WILL YOUR PARTICIPATION REQUIRE?

If you decide to be in this study, the following routine and/or experimental procedures will be performed:

Your participation in the study will last up to 12 months after your neck spine surgery. For the study, your participation will include 7 study visits. The visits include your pre-operative visit, the first and second days after your surgery, while you are in the hospital, and when you return to see your surgeon for routine post-operative follow at 4-6 weeks, 3 months, 6 months and 12 months.

This study will select your treatment by chance. You will be assigned at random, similar to a flip of a coin, to one of two study groups that will receive different treatments. The possible treatments you may receive during surgery are one of the following: 1) neck spine surgery as planned with your surgeon (standard of care) or 2) neck spine surgery with topical steroid application. You will be blinded to the treatment you are assigned to receive. It is not known if any treatment you receive will benefit you. The likelihood of being assigned one of these treatments is a one in two chance. It is not known if any treatment you receive will benefit you. It is hoped the knowledge gained will benefit others in the future.

You will complete questionnaires at each study visit that ask you about swallowing problems affecting your quality life and how often you have problems consuming liquids and solid foods. If you are unable to return for your routine follow-up visits, we will contact you by phone about these questions.

Study Visit #	Surveys	Randomization	Surgery	X-Rays	CT	Physical Exam	Phone Contact
#1 Pre-op	X	X	SOC*	SOC	SOC	SOC	
#2 Post-op Day 1	X			SOC [†]		SOC	
#3 Post-op Day 2	X					SOC	
#4 Post-op week 4-6 (± 1 week)	X			SOC		SOC	X
#5 Post-op month 3 (± 2 weeks)	X			SOC		SOC	X
#6 Post-op month 6 (± 4 weeks)	X			SOC		SOC	X
#7 Post-op month 12 (± 8 weeks)	X			SOC	SOC	SOC	X

X= Research procedures

SOC= Standard of care (care you would receive if you were not participating in this study)

***= If randomized to receive the study medication, this is considered a research procedure**

[†]= Depending on patient condition Post-op Day 1 x-rays will be collected within 24-72 hours of the operation

You and/or your insurance will be responsible for any costs of all procedures performed that are standard of care, that is, care that you would receive even if you were not in this study.

| A total of ~~400~~120 participants will participate in this study at HSS.

Your participation will involve a total of 7 study visits. Most visits are expected to last 30 minutes.

3. WHAT ADVERSE (BAD) EFFECTS CAN HAPPEN FROM BEING IN THE STUDY? WHAT RISKS ARE KNOWN ABOUT THE STUDY DRUG/STUDY DEVICE?

There are risks associated with your surgery, which your surgeon will discuss with you prior to surgery.

The known effects, discomforts and foreseeable risks of physical, psychological, sociological, or other harm which you may reasonably expect to occur from being in this study are: none. Potential risks which are unlikely to occur, but which may theoretically occur, are related to topical administration of steroid and may include infection, increased blood glucose, allergic reaction, and failure of fusion of the bone. We consider the likelihood of these risks to be very low.

Participation in this research involves the potential risk of a breach of confidentiality to your stored health information. HSS tries to minimize those risks by (i) removing some direct identifiers from stored information [(i.e., names, social security numbers, medical record

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numbers); (ii) securing, in a separate location, and limiting access to information that would identify you; and (iii) limiting access to information stored to HSS investigators.

There may be risks or side effects that are unknown at this time. If we learn about new risks that may affect your willingness to continue your participation, we will make you aware of them and you will be asked to re-consent to continue your participate in the study.

Your condition may not get better from being in this study.

4. WHAT BENEFIT CAN YOU EXPECT?

This study includes experimental/investigational treatments which may or may not give you immediate benefit or any benefit. Potential direct benefit would be improved swallowing post-operatively. The knowledge gained may benefit others in the future.

5. COST

There will be no cost to you for participation in this study because this study does not involve any additional visits, tests, or procedures. If you are randomized to the steroid treatment group the cost of the steroid will be covered by the study.

You will still be responsible for the cost of your medical care, and for any co-pays, deductibles, and co-insurance associated with your medical care, just as you would be if you were not part of this study.

HSS is committed to providing financial assistance when financially warranted and consistent with its resources, regardless of age, gender, religion, race or sexual orientation. So if you do not have health insurance, or if your health insurance does not pay for your medical care, you may seek financial assistance from HSS. Eligibility determinations are made on a case-by-case basis in accordance with HSS's financial assistance policy. You will be responsible for any costs not covered by financial assistance, which could be all of the costs (if HSS determines that you are not eligible for financial assistance) or some of the costs (if financial assistance awarded by HSS does not cover all of the costs). For more information about the Financial Assistance Program or to request a [Financial Assistance Application](#) call (212) 606-1505 to speak with a Financial Assistance Counselor or you can visit the following site: <http://www.hss.edu/patient-financial-assistance-notice.asp>.

6. PREGNANCY

Due to inherent risks, HSS policy prevents pregnant women from receiving the type of intervention needed to qualify for this research study. Therefore, women who are pregnant or nursing a child may not participate in this study. You must confirm that, to the best of your knowledge, you are not now pregnant, and that you do not intend to become pregnant during the next year. If you suspect that you have become pregnant during this study, you must notify the study doctor immediately.

7. PAYMENT FOR PARTICIPATION

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

8. COMMERCIAL ISSUES: YOUR RIGHTS IN THE RESULTS OF THE STUDY

There are no plans to compensate you for the use of the findings of this study, or any of the information or biologic materials (such as blood or tissue) collected from you during the study, even if they are used to develop or make a commercial product (such as a drug, device, biologic substance, or test).

9. ALTERNATIVES: WHAT OTHER TREATMENT IS AVAILABLE IF YOU DON'T WANT TO BE IN THE STUDY?

You do not have to participate in this study to receive treatment for your condition. If your spine surgeon routinely administers intraoperative topical steroids, you will receive them without needing to participate in the study.

You should ask the study doctor about other alternative treatments that may be available for your condition.

10. WHO WILL BE ABLE TO SEE YOUR RECORDS AND PERSONAL INFORMATION AND KNOW THAT YOU ARE IN THE STUDY?

Federal regulations give you certain rights related to your health information. These include the right to know who will be able to see your information and why they will be able to see it. The study doctor must obtain your authorization (permission) to use or give out any health information that might identify you.

What information may be used or given to others?

If you choose to be in the study, the study doctor will get personal information about you. The information might identify you. The study doctor may also get information about your health including:

- Medical and research records
- Records about phone calls
- Records about your study visits
- Records of physical exams
- Laboratory, x-ray, and other test results
- Questionnaires
- Records about any study device you received

Who may use, disclose, or receive my information?

The following person(s) class(es) of persons, and/or organization(s) may use, disclose, or receive my information:

- The Principal Investigator and other Investigators for this study, including your study doctor.
- The research coordinator, research nurses, and other members of the HSS research team working on this study.
- Every research site for this study, including Hospital for Special Surgery and its affiliates, New York-Presbyterian Hospital, and Memorial Sloan-Kettering Cancer Center. This includes the research staff and medical staff at each institution.
- The Patient Advocate or Research Ombudsman at these institutions.
- Staff members of HSS responsible for administering clinical trials and other research activities.
- Any laboratories and other individuals and organizations that analyze your health information for this study.
- Any health care provider that you have used in the past or may use up to the time this study ends.
- The United States Food and Drug Administration (FDA), the federal Office for Human Research Protections (OHRP), any federal agency that provides support for this study, and any federal, state, or local agency responsible for overseeing HSS, the study doctor, or any other member of the HSS research team involved in this study.
- The members and staff of the affiliated Institutional Review Boards (IRBs) at HSS, New York-Presbyterian Hospital, and Memorial Sloan-Kettering Cancer Center. An IRB is a committee of health care providers, community representatives, and others that initially approves and periodically reviews biomedical and behavioral research that involves human subjects in order to protect the rights, safety and welfare of study participants.
- Data Safety Monitoring Boards and others authorized to monitor the conduct of this study for safety or quality assurance, for example a Clinical Events Committee.

Why will this information be used and/or given to others?

Your health information may be given to others to carry out this study. The sponsor will analyze and evaluate the results of this study. People working for the sponsor also visit HSS and other research sites to make sure this study is being done correctly.

Your health information may be given to the FDA. It may also be given to governmental agencies in other countries. This is done so the sponsor can get approval to market new products resulting from this study. Your information may also be used to meet the reporting requirements of governmental agencies.

The results of this study may be published in scientific journals or presented at medical meetings, but your identity will not be disclosed.

What if I decide not to give permission to use and give out my health information?

By signing this informed consent form, you are giving permission to use and give out your health information as described above. If you refuse to give permission, you cannot be in this study.

May I review or copy the information obtained from me or created about me?

You have the right, in accordance with Hospital policy and applicable law, to review and copy your health information that is created or obtained in the course of this study. However, if you decide to be in this study and sign this informed consent form, you will not be able to look at or copy your information until after the study is completed if doing so would impact the validity of the study (for example, if the study is “blinded” so that during the study you will not know what treatment or other intervention you are receiving).

May I revoke (take back) my permission?

Yes. Your permission will never expire unless you revoke it. To revoke your permission, you must write to the study doctor at Hospital for Special Surgery, 535 East 70th Street, New York, NY 10021.

You may revoke your permission to use and disclose your health information at any time. If you revoke your permission, you cannot continue to participate in this study.

After you revoke your permission, no new health information that might identify you will be gathered. Information that has already been gathered may still be used and given to others. This would be done if the information is needed for this study to be reliable.

Is my health information protected after it has been given to others?

Some persons who receive your health information may not be required to protect it, and they may share your information with others without your permission, if permitted by laws governing them. Therefore, there is a risk that your information will be released to others without your permission.

11. CONFLICT OF INTEREST NOTIFICATION

HSS is concerned about possible conflicts of interest in research, and has policies that require all investigators and senior research staff to report to HSS significant financial interests (such as stock ownership, royalty payments, and consulting agreements) and relationships (such as membership on a scientific advisory board) that are related to their research studies. When an investigator reports a significant financial interest or relationship that relates to one of his/her

studies, HSS's Conflict of Interest Committee for Research reviews the information to evaluate the risk that the interest or relationship might influence how the investigator conducts the study or interprets the results of the study. HSS may also take steps to minimize that risk.

☒ The Conflict of Interest Committee for Research has determined that there are no conflicts of interest associated with this study.

☐ The Conflict of Interest Committee for Research has determined that there is a potential conflict of interest associated with this study. Please read the information below carefully.

12. VOLUNTARY PARTICIPATION/WITHDRAWAL

Your decision to take part in this study is completely voluntary. You are free to choose not to take part in the study and may change your mind and withdraw at any time. Your relationship with physicians at HSS and your medical care at HSS, now or in the future, will not be affected in any way if you withdraw or refuse to participate. You will not lose any benefits to which you are otherwise entitled.

The study doctor and/or the sponsor may terminate your participation in this study at any time without your consent if, in their judgment, it is inadvisable for you to continue.

13. COMPENSATION FOR INJURY

If you are injured as a result of participating in this study, the study doctor, other members of the research team, or other HSS professional medical staff will provide you with emergency medical treatment (or arrange to have such treatment provided to you), and will assist you in obtaining appropriate follow-up medical treatment. However, there is no plan to routinely provide compensation for additional medical care or other costs.

Your health insurance may or may not pay for treatment of injuries as a result of your participation in this study.

14. SOURCE OF FUNDING

Funding for this study will be provided by the Spine Service at Hospital for Special Surgery.

15. QUESTIONS

If you have any additional questions later on, or if you wish to report a medical problem that may be related to this study, Dr. Todd J. Albert can be reached at (212) 606-1004 during office hours and after business hours.

If you have any questions about your rights as a participant in this study or any questions about your participation that you would like to ask an institutional representative who is not part of this study, you can call the Manager of the HSS Institutional Review Board at (212) 774-7154.

If you would like to have more information about the Hospital's financial disclosure review process in general, or in regard to this study, you may contact the Hospital's Office of Legal Affairs at (212) 606-1592. You may also ask the Hospital's patient advocate at (212) 774-2403, to arrange for you to have this information.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

Agreement to Participate: Witnessing and Signature

To be in this study, you or your legal representative must sign the next page of this informed consent form. By signing the next page, you are voluntarily agreeing to be in this study at HSS.

Before signing, you should be sure of the following:

- You have read all of the information in this “Informed Consent to Participate in Research” form (or had it read to you).
- You have discussed the implications of your being in this study with your doctor, your study doctor and/or the study coordinator.
- You have had the chance to ask questions about this study.
- You received answers to your questions.
- If you did not understand any of the answers, you asked the study doctor or the study coordinator to explain them to you.
- The information given to you is based on what is now known about the study drug(s), device(s), or procedure(s). There may be other risks or complications that are not known at this time.
- You have had time to think about the information and decide whether or not to be in the study.

Please check one of the following:

- ☐ I AM NOT in another research study at this time.
- ☐ I AM in another research study at this time.

If you decide to be in this study:

- You are expected to follow the study procedures.
- You are expected to provide the information needed by the study doctor, the study coordinator, nurses, or other staff members for the study.
- You will be told in a timely manner of any significant new information that may affect your willingness to stay in the study.
- You may freely choose to stop being in the study at any time.

By signing below, you are voluntarily agreeing to be in this study.

You must be given a signed copy of this informed consent form to keep for yourself.

_____	_____	_____
Print Name of Participant	Signature of Participant	Date

_____	_____	_____
Print Name of Parent/Legal Guardian (if applicable) ¹	Signature of Parent/Legal Guardian	Date

_____	_____	_____
Print Name of Person Obtaining Consent	Signature of Person Obtaining Consent	Date

As an HSS representative, please sign here to indicate that you have given a signed copy of this informed consent form to the participant

NOTE TO INVESTIGATORS:

- **THE ORIGINAL OF THIS INFORMED CONSENT FORM MUST BE PLACED IN THE PARTICIPANT'S STUDY FILE.**
- **A SIGNED COPY OF THIS INFORMED CONSENT FORM MUST BE GIVEN TO THE PARTICIPANT.**
- **A COPY OF THE INFORMED CONSENT FORM MUST BE PLACED IN THE PARTICIPANT'S HOSPITAL MEDICAL RECORD IF THE PARTICIPANT IS (OR WILL BE) HOSPITALIZED AT ANY TIME DURING THE STUDY.**

¹ The parent or legal guardian of a child participant should sign this form on behalf of the child. The signature of one parent is sufficient when the research is of minimal risk to the child, or when the research presents the prospect of direct benefit to the child. The signature of both parents is required when the research involves greater than minimal risk with no prospect of direct benefit to the child. The requirements for signature of both parents may be waived if one parent is deceased, unknown, incompetent, or not reasonably available, or when one parent has sole legal responsibility for the care and custody of the child. If the participant is a child who is capable of giving assent, the child should also sign the attached Assent Form.

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