Dysphagia Following Anterior Cervical Spine Surgery; Single Dose Steroid Vs Saline (DysDexVSSal)

NCT03711474

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More Than Minimal Risk
Consent and HIPAA Form

Principal Investigator	Scott Daffner, MD
Department	Orthopaedics
Protocol Number	1804077978
Study Title	Impact of Single Dose Perioperative Steroids on Dysphagia Following Anterior Cervical Spine Surgery: A Randomized, Prospective, Double-Blind Study
Co-Investigator(s)	Sanford Emery, MD; John France, MD; Shari Cui, MD; Cara Sedney, MD; Robert Marsh, MD; Sanjay Bhatia, MD
Study Personnel	Paige Harman, Patricia Dekeseredy, Jenn Eicher

Contact Persons

In the event you experience any side effects or injury related to this research, you should contact Dr. Scott Daffner at (304) 293-2779. (After hours contact WVU Healthcare at 304-598-4000 and ask for the Orthopaedic resident on call.) If you have any questions, concerns, or complaints about this research, you can contact Dr. Scott Daffner (304) 293-2779.

For information regarding your rights as a research subject, to discuss problems, concerns, or suggestions related to the research, to obtain information or offer input about the research, contact the Office of Research Compliance at (304) 293-7073.

Introduction

You, _____, have been asked to participate in this research study, which has been explained to you by _____. This study is being conducted by Scott Daffner, MD; Sanford Emery, MD, MBA, John France, MD, Shari Cui, MD, in the Department of Orthopaedics, and Cara Sedney, MD; Robert Marsh, MD; Sanjay Bhatia, MD, in the Department of Neurosurgery at West Virginia University.

Purpose(s) of the Study

The purpose of this study is to find out if giving one dose of steroid during cervical spine surgery helps reduce difficulty swallowing (dysphagia) after surgery.
WVU expects to enroll approximately 80 subjects.

Description of Procedures

This study involves randomization (like flipping a coin) to either the group receiving a single dose of steroid during surgery or the group receiving a single dose of saline during surgery. This is a double blind study, which means the surgeon, anesthesiologist, and the patient will not know what group assignment (saline or steroid) the patient has received. The in-patient pharmacy will prepare IV bags that are labeled for the study but that are blinded as to medication/saline labels.

You will receive one dose of the study drug during surgery. You will be asked to fill out three short surveys regarding swallowing difficulties; the Bazaz dysphagia scale, the Dysphagia Short Questionnaire and the E-10 survey. This will take approximately 5 minutes to complete. You do not have to answer all the questions. You will have the opportunity to see the questionnaires before signing this consent form. You will also be asked to complete standard of care questionnaires via a tablet computer or via email at the visit before your surgery and at 1 year post-surgery. The questionnaires allow us to determine how you are doing before and after surgery. They are Patient Reported Outcome Measures (PROMS). It will take you approximately 15 minutes to complete the PROMS.

Both groups will be asked to complete the short surveys before their surgery and postoperatively at Day 1, Day 2, Week 1, Week 2, Month 1, 3, 6, and 12. On Day 2 after surgery, if you are discharged, the surveys will be done via phone call. If you are still in the hospital, the Research Coordinator will come to your room and have you complete the surveys or call you. At Week 1, you will also receive a phone call to compete the surveys as you will have no follow up visit scheduled at that time. You may receive phone calls for all the following follow up times, Week 2, months 1, 3, 6, and 12 to complete the surveys if the follow up visit is not scheduled at the time the surveys should be completed. We will evaluate which patients fare better regarding prevalence and severity of dysphagia (difficulty swallowing); those who have been administered steroid or those who have been administered saline, by analyzing the results from the surveys and reviewing medical records.

Risks and Discomforts

Dexamethasone, the steroid used in this study, may cause a possible elevation of serum glucose levels in diabetic patients. All patients in the study are monitored after surgery with routine postoperative laboratory testing. An elevation of serum glucose levels would be detected and treated during routine monitoring. This study may involve risks to the unborn child. For this reason, women who are pregnant will not be accepted. If you are a woman who could become pregnant, you will not be allowed to participate in this study until you have had a pregnancy test and the test has indicated that you are not pregnant. You must use a medically approved method of birth control through the day of surgery.

Alternatives

You do not have to participate in this study.

An alternative is to seek a hospital that routinely gives steroids to patients undergoing anterior, cervical spine surgery, as this is standard of care for some hospitals.

Benefits

Possible benefits that may result from your participation include the improvement of your health, but since it is not known whether either therapy will be effective in your case, you may not receive any benefit or your condition may worsen. The knowledge gained from this study may eventually benefit others.

Financial Considerations

You may wish to consult your insurance carrier prior to entering this study.

There are no special fees for participating in this study, but any expense associated with current therapy or treatment of side effects will be billed to you or to your insurance company.

Voluntary Compensation

If you are injured as a result of this research, treatment will be available. Responsibility for this treatment will be borne by you. In the event that you are physically injured as a result of participating in this research, care will be available. You will however, be responsible for the charges for the care. There is no commitment to provide any compensation for research-related injury. You should realize, however, that you have not released this institution from liability for negligence. Please contact the investigator, Scott Daffner at (304-293-2779) if you are injured or for further information.

Confidentiality

Any information about you that is obtained as a result of your participation in this research will be kept as confidential as legally possible. Your research records and test results, just like hospital records, may be subpoenaed by court order or may be inspected by the study sponsor or federal regulatory authorities (including the FDA if applicable) without your additional consent.

In addition, there are certain instances where the researcher is legally required to give information to the appropriate authorities. These would include mandatory reporting of infectious diseases, mandatory reporting of information about behavior that is imminently dangerous to your child or to others, such as suicide, child abuse, etc.

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by US law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

HIPAA

We know that information about you and your health is private. We are dedicated to protecting the privacy of that information. Because of this promise, we must get your written authorization (permission) before we may use or disclose your protected health information or share it with others for research purposes.

You can decide to sign or not to sign this authorization section. However, if you choose not to sign this authorization, you will not be able to take part in the research study. Whatever choice you make about this research study will not have an effect on your access to medical care.

Persons/Organizations Providing the Information

Patient/West Virginia University Hospitals

Persons/Organizations Receiving the Information

- The research site(s) carrying out this study. This includes UHA or UHA Affiliated, WVU, WVU Hospitals. It also includes each site's research staff and medical staff
- Health care providers who provide services to you as part of this research study.
- Laboratories and other people and groups that look into your health information as part of this study in agreement with the study protocol.
- The United State Department of Health and Human Services (which includes the National Institutes of Health (NIH), Food and Drug Administration (FDA)) and other groups that have the right to use the information as required by law.
- The members and staff of any Institutional Review Board (IRB) that oversees this research study.
- West Virginia University Office of Research Compliance and Office of Sponsored Programs.

The Following Information Will Be Used

Information from your existing medical records and new information about you that is created or collected during the study such as: history and physicals, clinic visit notes, nursing and staff notes, laboratory results, x-rays, EKG results, demographic data, pulmonary tests, imaging scans and study forms.

The Information is Being Disclosed for the Following Reasons

- Publication of study results (without identifying you)
- Other research purposes such as reviewing the safety or effectiveness of the study drug; developing a better understanding of anterior, cervical spine surgery and dysphagia

You May Cancel this Authorization at Any Time by Writing to the Principal Investigator

Dr. Scott Daffner, West Virginia University, Department of Orthopaedics, 3400 Health Science Center South, Morgantown, WV 26506-9196

If you cancel this authorization, any information that was collected already for this study cannot be withdrawn. Once information is disclosed, according to this authorization, the recipient may re-disclose it and then the information may no longer be protected by federal regulations.

You have a right to see and make copies of your medical records. You will not be able to see or copy your records related to the study until the sponsor has completed all work related to the study. At that time you may ask to see the study doctor's files related to your participation in the study and have the study doctor correct any information about you that is wrong.

This authorization will expire at the end of the study unless you cancel it before that time (or has a specific expiration date).

Voluntary Participation

Participation in this study is voluntary. You are free to withdraw your consent to participate in this study at any time.

Refusal to participate or withdrawal will not affect [your class standing or grades, as appropriate] and will involve no penalty to you. Refusal to participate or withdrawal will not affect your future care, or your employee status at West Virginia University.

In the event new information becomes available that may affect your willingness to participate in this study, this information will be given to you so that you can make an informed decision about whether or not to continue your participation.

You have been given the opportunity to ask questions about the research, and you have received answers concerning areas you did not understand.

Upon signing this form, you will receive a copy.

I willingly consent to participate in this research.

Signatures

Signature of Subject

_____

Printed Name Date Time

_____

The participant has had the opportunity to have questions addressed. The participant willingly agrees to be in the study.

Signature of Investigator or Co-Investigator

_____

Printed Name Date Time

_____

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Subject's
Initials_____
Date_____