NCT02359825

Nerve Repair Using Hydrophilic Polymers to Promote Immediate Fusion of Severed Axons and Swift Return of Function

6/11/2026

eICD V. 8-14-22

Please read the consent form carefully. If you consent to participating in the study, please complete the survey below by entering your name and age. Then, sign your name and today's date below. Thank you!

1) MRN

_____

VUMC Institutional Review Board
Informed Consent Document for Research Study Title: Nerve repair using hydrophilic polymers to promote immediate fusion of severed axons and swift return of function: A pilot study

Version Date: August 14, 2021

PI: Wesley Thayer, MD, PhD

Date of IRB Approval:

Date of IRB Expiration:

2) Name of participant

_____

3) Age

_____

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

Date of IRB Approval: 10/09/2025
Date of Expiration: 10/08/2026

Key information about this study:

The U.S. Department of Defense (DoD) is the sponsor of the study.

You are being asked to take part in this research study because you have suffered a traumatic nerve injury to the upper extremity that requires surgical repair. The purpose of this study is to modify current nerve repair strategies by introducing a commonly used drug, polyethylene glycol (PEG) to fuse your divided nerve. PEG is approved for other uses in humans but its use in fusing nerves is considered investigational. Occasionally with nerve injuries there is missing tissue.

Your samples and information about you may be made available to others to use for research. To protect your privacy, we will not release your name. You will not receive any benefit as a result of the tests done on your samples. These tests may help us learn more about the causes, risks, treatments, or how to prevent this and other health problems. Your samples may be used to make new products or tests. These may have value and may be developed and owned by the study staff, Vanderbilt University, and/or others. If this happens, there are no plans to provide money to you.

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study. Your medical record will contain a note saying you are in a research study and may contain some research information about you. Anyone you authorize to receive your medical record will also get this information.

Side effects and risks that you can expect if you take part in this study:

We anticipate low risk to you given the history of the safety of PEG as there will be minimal systemic absorption since they will only be used topically as an irrigation and sealant. The PEG treatment is washed away after one minute to minimize side effects including inflammation at the injection site to abnormal increase in certain blood components such as red blood cells.

Risks that are not known:

Because this treatment is investigational, meaning non-FDA approved, FDA to enhance participant understanding that may be risks that we do not know at this time.

Good effects that might result from this study:

The benefits to science and humankind that might result from this study: Through an understanding of the rate and degree of recovery following nerve repair with the use of PEG, future patients may be more accurately informed of the expected results.

There will be no benefits to participants who are randomized to the Standard of Care group. There may be improvements in sensation in the group receiving the use of PEG during nerve repair with autografting, but there is no guarantee.

Procedures to be followed:

All follow-up clinic visits are standard of care treatment plan.

- Surgery
- Follow-up clinic visits after surgery
- There are total 5 follow-up visits after repair at:
- 1-21 days
- 22-40 days
- 60-120 days
- 150-210 days
- 330-390 days
- Injury and repair hand exam which include pain assessment, hand function and sensation evaluation
- Rehabilitation evaluation
- Injury site self-evaluation questionnaires

Payments for your time spent taking part in this study or expenses:

You will receive $100 payment per visit for your time and participation in this study.

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There are no plans for Vanderbilt to pay for any injury caused by the usual care you would normally receive for treating your illness or the costs of any additional care. There are no plans for Vanderbilt to give you money for the injury.

Costs to you if you take part in this study:

If you agree to take part in this research study, you and/or your insurance will not have to pay for the tests and treatments that are being done only for research. However, you are still responsible for paying for the usual care you would normally receive for the treatment of your illness. This includes treatments and tests you would need even if you were not in this study. These costs will be billed to you and/or your insurance.

You have the right to ask what it may cost you to take part in this study. If you would like assistance, financial counseling is available through the Vanderbilt Financial Assistance Program. The study staff can help you contact this program. You have the right to contact your insurance company to discuss the costs of your routine care (non-research) further before choosing to be in the study. You may choose not to be in this study if your insurance does not pay for your routine care (non-research) costs and your doctor will discuss other treatment plans with you.

Payment in case you are injured because of this research study:

If it is determined by Vanderbilt and the Investigator that an injury occurred as a direct result of the tests or treatments that are done for research, then you and/or your insurance will not have to pay for the cost of immediate medical care provided at Vanderbilt to treat the injury.

There are no plans for Vanderbilt to pay for any injury caused by the usual care you would normally receive for treating your illness or the costs of any additional care. There are no plans for Vanderbilt to give you money for the injury.

Who to call for any questions or in case you are injured:

If you should have any questions about this research study or if you feel you have been hurt by being a part of this study, please feel free to contact Wesley Thayer, MD at 615-936-0160. If you cannot reach the research staff, please page the study doctor at 615-831-6377.

For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the VUMC Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

Reasons why the study doctor may take you out of this study:

Your study doctor may decide to take you out of the study early. If you are taken out of the study, you will be told the reason why.

What will happen if you decide to stop being in this study?

If you decide to stop being part of the study, you should tell your study doctor. Deciding to not be part of the study will not change your regular medical care in any way.

You may withdraw from this study at any time by sending written notice to the study doctor. When you withdraw your permission, no new health information which might identify you will be gathered after that date. Information that has already been gathered may still be used and given to others. This would be done if it were necessary for the research to be reliable.

Clinical Trials Registry:

A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. 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 Web site at any time.

Confidentiality:

Vanderbilt may share your information, without identifiers, to others or use it for other research projects not listed in this form. Vanderbilt, Dr. Thayer and his staff will comply with any and all laws regarding the privacy of such information. There are no plans to pay you for the use or transfer of this de-identified information. Information will be stored in a password-protected database and only Dr. Thayer and his staff will have access to this information. Codes will be used in place of names whenever possible and stored in a locked cabinet and only study staff will have access to research information.

The Department of Defense (DoD) or DoD representatives will have access to the study records.

This study may have some support from the National Institutes of Health (NIH). If so, your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means. It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

Privacy:

Any samples and information about you may be made available to others to use for research. To protect your privacy, we will not release your name. You will not receive any benefit as a result of the tests done on your samples. These tests may help us or other researchers learn more about the causes, risks, treatments, or how to prevent this and other health problems.

Your samples may be used to make new products or tests. These may have value and may be developed and owned by the study staff, Vanderbilt University, Vanderbilt University Medical Center, and/or others. If this happens, there are no plans to provide money to you.

Study Results:

The study results will be kept in your research record for at least six years after the study is finished. At that time, the research data that has not been put in your medical record will be kept for an unknown length of time. Any research data that has been put into your medical record will be kept for an unknown length of time.

Authorization to Use/Disclose Protected Health Information

What information is being collected, used, or shared?

To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Vanderbilt University Medical Center and others) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Who will see, use or share the information?

The people who may request, receive or use your private health information include the researchers and their staff. Additionally, we may share your information with other people at Vanderbilt, for example if needed for your clinical care or study oversight. By signing this form, you give permission to the research team to share your information with others outside of Vanderbilt University Medical Center. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers and other agents and contractors used by the study team. We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

Do you have to sign this Authorization?

You do not have to sign this Authorization, but if you do not, you may not join the study.

How long will your information be used or shared?

Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

What if you change your mind?

You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

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If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

4) Date

_____

5) Signature of patient/volunteer

_____

Consent obtained by:

6) Date

_____

7) Signature

_____

8) Printed Name and Title

_____

Consent Notes

Patient/Participant was consented for IRB#191655.

Initial consent was obtained in a private, confidential and safe setting. The informed consent form (ICF) was provided in the subject's primary language. The patient/participant was given the opportunity to read the ICF.

ICF was discussed in full detail and the opportunity was given for patient/participant to ask questions. Questions regarding the study were answered. ICF was signed by patient/participant before any research-related procedures were performed. Patient/participant was present during the consent process. Study contact information was provided to patient/participant. A copy of the signed consent was given to the patient/participant.

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