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Surgical Treatment of Post-surgical Mastectomy Pain Utilizing the Regenerative Peripheral Nerve Interface

NCT04530526

UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: Surgical treatment of post-surgical mastectomy pain utilizing the regenerative peripheral nerve interface (RPNI)

Company or agency sponsoring the study: Pending funding from National Institutes of Health

Names, degrees, and affiliations of the principal investigator and study coordinator:

Principal Investigator: David L. Brown, MD, Section of Plastic Surgery, University of Michigan

Study Coordinator: Jennifer B. Hamill, MPH, Section of Plastic Surgery, University of Michigan

1.1 Key Study Information

You may be eligible to take part in a research study. This form contains important information that will help you decide whether to join the study. Take the time to carefully review this information. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others such as your family, friends, or other doctors about joining this study. If you decide to join the study, you will be asked to sign this form before you can start study-related activities. Before you do, be sure you understand what the research study is about.

A research study is different from the regular medical care you receive from your doctor. Research studies hope to make discoveries and learn new information about diseases and how to treat them. You should consider the reasons why you might want to join a research study or why it is not the best decision for you at this time.

Research studies do not always offer the possibility of treating your disease or condition. Research studies also have different kinds of risks and risk levels, depending on the type of the study. You may also need to think about other requirements for being in the study. For example, some studies require you to travel to scheduled visits at the study site in Ann Arbor or elsewhere. This may require you to arrange travel, change work schedules, find child care, or make other plans. In your decision to participate in this study, consider all of these matters carefully.

This research collects health-related information to examine treatments for chronic post-mastectomy pain. In particular, we are interested in patient reported outcomes after undergoing a nerve surgery called Regenerative Peripheral Nerve Interface (RPNI). This research will examine post-mastectomy pain before and after the treatment you receive through the Michigan Medicine Plastic Surgery Clinic.
There can be risks associated with joining any research study. The type of risk may impact whether you decide to join the study. For this study, some of these risks may include loss of confidentiality. More detailed information will be provided later in this document.

This study may not offer any benefit to you now but may benefit others in the future by improving treatment of post-mastectomy pain. More information will be provided later in this document.

We expect the amount of time you will participate in the study will be about 12-18 months.

You can decide not to be in this study. Even if you decide to join the study now, you are free to leave at any time if you change your mind.

More information about this study continues in Section 2 of this document.

2. PURPOSE OF THIS STUDY

2.1 Study purpose:
Some patients who undergo mastectomy or partial mastectomy (where breast tissue is removed from the chest wall) experience long-term nerve pain in their chest area. This study evaluates patient reported outcomes and reported pain before and after undergoing a nerve surgery called Regenerative Peripheral Nerve Interface (RPNI).

3. WHO MAY PARTICIPATE IN THE STUDY

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

The study will recruit adults at least 18 years old seeking surgical treatment for severe chronic post-mastectomy pain. Eligible patients must have undergone mastectomy or partial mastectomy (lumpectomy) at least six months prior to the consultation at either Michigan Medicine's Multidisciplinary Peripheral Nerve Clinic or the Plastic Surgery Clinic during the enrollment period, and be fluent in English.

Patients will be excluded if they have undergone previous surgical management for their pain or have signs/symptoms which are not suggestive of neuropathic pain. Pregnant women will also be excluded.

3.2 How many people are expected to take part in this study?
We expect to enroll 35 patients from the University of Michigan into this study.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?
By participating in this study, you will be asked to do the following:

1. Complete study questionnaires about pain, medication use, anxiety and depression at regular intervals.
2. Allow researchers to review your medical records and collect clinical data about you for the study.

Subject Responsibilities: As a subject participating in this research study, you have certain responsibilities that may apply to this study, such as ensuring that you arrive at all of your scheduled appointments, take your study medication as directed, and report any adverse reactions you may have during the study.

4.2 How much of my time will be needed to take part in this study?
Total time for study participation will be about 2 ¼ to 3 ¼ hours as follows:

Baseline Visit (45-60 minutes) – If you express interest in participating in the study, a research coordinator will explain the study to you, answer all of your questions and ask you to sign a written informed consent document. This might take as long as 15 minutes. After consenting, you will complete a panel of questionnaires that will take approximately 25-45 minutes of your time, either online or on paper.

Pre-RPNI Surgery Visit (30-45 minutes) – Shortly before your scheduled surgery, you will complete a panel of questionnaires that will take approximately 30-45 minutes of your time, either online or on paper.

Three Months Post-Surgery Visit (30-45 minutes) - Approximately three months after your final intercostal nerve surgery (unless you decide not to have surgery), you will complete a panel of questionnaires that will take approximately 30-45 minutes of your time, either online or on paper.

Nine Months Post-Surgery Visit (30-45 minutes) - Approximately nine months after your final intercostal nerve surgery (unless you decide not to have surgery), you will complete a final panel of questionnaires that will take approximately 30-45 minutes of your time, either online or on paper.

4.3 When will my participation in the study be over?
Participation in this study will last for approximately 12-18 months – about 3 months before surgery and 9 months after your final intercostal nerve surgery. In addition to the time above, we will collect information from your medical records for this time period.

4.4 What will happen with my information and/or biospecimens used in this study?
Your biospecimens and collected information may be shared with the study's sponsor, the National Institutes of Health (NIH) if funded.

With appropriate permissions, your biospecimens and collected information may also be shared with the study's sponsor (NIH) other researchers, here, around the world, and with companies.

Your identifiable private information or identifiable biospecimens may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

Your collected information will be added to our study's database and analyzed with all other data. Findings from the combined data will be used for reporting purposes, data for a future larger study and for publications. Your information will only be used after it is de-identified and when combined with other data (in aggregate form).

Besides the information about the main study, the following information is specific to unspecified future use of identifiable data and/or biospecimens. We would also like your permission to keep the medical information collected in the main study, so that we may study it in future research. The future research may be similar to this study or may be completely different.

You can take part in the main study even if you decide not to let us keep your medical information for future research.

If you give us your permission, we may use your medical information for future research. Even if you give us permission now to keep some of your medical information, you can change your mind later and ask us to destroy it. Keep in mind, however, that once we have analyzed your data, we may not be able to take the information out of our research.

We may share your medical information with other researchers, so that they can use it in their research. Their research may be similar to this study or may be completely different. Once we have shared your medical information with other researchers, we will not be able to get it back.

Future use of your identifiable data will be conducted in compliance with applicable regulatory requirements.

You will not find out the results of future research on your medical information. Allowing us to do future research on your medical information will not benefit you directly.

Your identifiable private information may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

The main risks to this study involve the risk of loss to confidentiality or privacy. This is also a risk that you will find the time to complete the questionnaires inconvenient.

The researchers will try to minimize confidentiality risks by assigning you a study ID number and using this number in relation to all of your study materials instead of your name. The 'key' linking your name and study ID will be stored securely in a password-protected program maintained by the Michigan Institute for Clinical and Healthcare Research (MICHR) at the University of Michigan. All data that is collected about you for the study will also be stored in this program. Only trained and approved study team members will have access to your study information. See Section 9 of this document for more information on how the study team will protect your confidentiality and privacy.

In terms of time and inconvenience, researchers are mindful of the value of your time and have worked to reduce the survey questions to the minimum needed to conduct this study. Also, in order to minimize risk and time, those procedures already being performed on subjects for diagnostic or treatment purposes will be used for the research. This includes chest ultrasounds and results of the physical exams performed during a clinic visit. We have also designed our data collection time points to coincide with the surgeon's normal post-operative follow-up schedule.

As with any research study, there may be additional risks that are unknown or unexpected.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?

If you find any of the questions from the study surveys disturbing, you may skip those items. If you have any other problems as a result of this research, please contact your surgeon immediately.

5.3 If I take part in this study, can I also participate in other studies?

Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

5.4 How could I benefit if I take part in this study? How could others benefit?

You may not receive any personal benefits from being in this study. However, others may benefit from the knowledge gained from this study.

6. ALTERNATIVES TO PARTICIPATING IN THE STUDY

6.1 If I decide not to take part in this study, what other options do I have?

Participation in this study is voluntary. If you choose not to participate, all treatment options, including RPNI surgery will remain available to you.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?

You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 "Contact Information".

7.2 Could there be any harm to me if I decide to leave the study before it is finished?

No.

7.3 Could the researchers take me out of the study even if I want to continue to participate?

Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?

The study will pay for research-related items or services that are provided only because you are in the study. If you are not sure what these are, see Section 4.1 above or ask the researchers for a list. If you get a bill you think is wrong, call the researcher's telephone number listed in Section 10.1.

You or your health plan will pay for all the things you would have paid for even if you were not in the study, like:

- Health care given during the study as part of your regular care
- Items or services needed to give you study drugs or devices
- Monitoring for side effects or other problems
- Deductibles or co-pays for these items or services.

If you do not have a health plan, or if you think your health plan may not cover these costs during the study, please talk to the researchers listed in Section 10 below or call your health plan's medical reviewer.

By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

8.2 Will I be paid or given anything for taking part in this study?

You will not be paid or given anything for taking part in this study.

8.3 Who could profit or financially benefit from the study results?
The researchers conducting the study:
Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

9. CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

The information below describes how the confidentiality of your research records will be protected in this study, and any sub-studies described in this document.

9.1 How will the researchers protect my information?
Your research information will be stored in a locked cabinet and in a secure database. When using data for reporting or publishing, only trends in the data set as a whole, not specific patient information, will be reported.
This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the SPONSOR which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of [list what will be reported, such as child abuse and neglect, or harm to self or others].

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

9.2 What protected health information (PHI) about me could be seen by the researchers or by other people? Why? Who might see it?
Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study.

Medical information and billing records are protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA). This type of information is called protected health information (PHI). PHI about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

- Hospital/doctor's office records, including test results (X-rays, blood tests, urine tests, etc.)
- Mental health care records (except psychotherapy notes not kept with your medical records)
- All records relating to your condition, the treatment you have received, and your response to the treatment
- Demographic information
- Personal identifiers

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- The researchers may need the information to check your test results or look for side effects.
- University, Food and Drug Administration (FDA) and/or other government officials, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
    - Make sure the study is done safely and properly
    - Learn more about side effects
    - Analyze the results of the study
- Insurance companies or other organizations may need the information in order to pay your medical bills or other costs of your participation in the study.
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- Information about your study participation may be included in your regular UMHS medical record.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article but would not include any information that would let others know who you are.

During the research, if we learn you are having thoughts about suicide or hurting yourself or others, the research staff will ask you more questions about your thoughts. Based on your response, the staff may provide you with help to get treatment. This may include:

- working with you to contact your doctor,
- contact a trusted family member, or a therapist to discuss your thoughts,
- or work with you on a plan that may include getting you to a hospital for safety.

9.3 What happens to information about me after the study is over or if I cancel my permission to use my PHI?

As a rule, the researchers will not continue to use or disclose information about you but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission, or the study is over.

Examples of reasons for this include:

- To avoid losing study results that have already included your information

- To provide limited information for research, education, or other activities. (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly.

As long as your information is kept within the University of Michigan Health System, it is protected by the Health System's privacy policies. For more information about these policies, ask for a copy of the University of Michigan "Notice of Privacy Practices". This information is also available on the web at http://www.uofmhealth.org/patient+and+visitor+guide/hipaa. Note that once your information has been shared with others as described under Question 9.2, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

9.4 When does my permission to use my PHI expire?

Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below). If you withdraw your permission, you may no longer be eligible to participate in this study.

10. CONTACT INFORMATION

10.1 Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Talk about study-related costs to you or your health plan
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator:	David L. Brown, MD
Mailing Address:	Domino's Farms, Lobby A 24 Frank Lloyd Wright Dr. Ste A1200 Ann Arbor, MI 48105-9484
Telephone:	734-998-6022
Email:	davbrown@med.umich.edu
Study Coordinator:	Jennifer B. Hamill, MPH
Mailing Address:	2130 Taubman Center 1500 E. Medical Center Dr. Ann Arbor MI 48109
Telephone:	570-559-7912
Email:	jenberry@med.umich.edu

You may also express a question or concern about a study by contacting the Institutional Review Board listed below:

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
Telephone: 734-763-4768

Fax: 734-763-1234
e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.

When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

You will receive a copy of the signed and dated informed consent.

Your signature in the next section means that you have received copies of all of the following documents:

- This "Consent to be Part of a Research Study" document. (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file and may be entered into your regular University of Michigan medical record.)*

12. SIGNATURES

Sig-A

Consent/Assent to Participate in the Research Study

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with _____. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Sig-D

Consent/Assent to Collect for Unspecified Future Research

This project involves the option to allow the study team to keep your identifiable specimens/data for use in future research. I understand that it is my choice whether or not to allow future use of my specimens. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

_____ Yes, I agree to let the study team keep my specimens for future research.

_____ No, I do not agree to let the study team keep my specimens for future research.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Sig-G

Principal Investigator or Designee

I have provided this participant and/or his/her legally authorized representative(s) with information about this study that I believe to be accurate and complete. The participant and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the study, including risks and benefits of participating.

Printed Legal Name: _____

Title: _____

Signature: _____

Date of Signature (mm/dd/yy): _____