

Official Title: Empowering Patients: A Randomized Controlled Trial (RCT) Investigating the Feasibility and Outcomes of Patient Self-Drain Removal after Ventral Hernia Repair

NCT06237855

IRB Approval Date: 07/17/2024

EMPOWERING PATIENTS: A RANDOMIZED CONTROLLED TRIAL
(RCT) INVESTIGATING THE FEASIBILITY AND OUTCOMES OF
PATIENT SELF-DRAIN REMOVAL AFTER VENTRAL HERNIA REPAIR

Informed Consent Form to Participate in Research
Todd Heniford, MD, Principal Investigator

SUMMARY

You are invited to participate in a research study. The purpose of this research is to show that patients can safely and correctly remove drains from their abdomen following ventral hernia surgery. You are invited to be in this study because you will undergo an elective ventral hernia repair and drains will be placed in your abdomen as part of the surgery. Your participation in this research will involve zero study visits not included as part of your normal post-operative follow-up and last about 30-days after your ventral hernia repair.

Participation in this study will involve you undergoing your ventral hernia repair as planned and then being randomized to 1 of 2 groups. If you are randomized into group 1, you will have your drains removed by a provider in our clinic as part of standard of care after surgery. If you are randomized into group 2, you will be trained to remove your drain at home without having to come into the clinic. All research studies involve some risks. A risk to this study that you should be aware of is the potential risk of infection if the drain is not removed properly. You may or may not benefit from participation in this study.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the study. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study please contact the Principal Investigator at [REDACTED].

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at [REDACTED] or the Wake Forest University Health Sciences Research Subject Advocate at [REDACTED].

INTRODUCTION

You are invited to be in a research study. Research studies help scientists learn new information that may help other people in the future. You are being asked to be in this study because you

Page 1 of 9
Adult Consent Form

Version: 1
Date: 07/01/2024

WFU School of Medicine
Institutional Review Board
IRB Number:IRB00100883
Meeting Date Approved 7/17/2024
Version Valid Until: 7/16/2025

have a ventral hernia that requires surgical repair. Your participation is voluntary. You do not have to be a part of this study if you do not want to. Please take your time in making your decision if you would like to join. Ask your study doctor or the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to determine if patients can safely and correctly remove drains at home following ventral hernia repair.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

100 people at this research site (Carolinas Medical Center) will take part in this study. In order to identify the 100 subjects needed, we may need to enroll as many as 150 because some people will not qualify to be included in the study or will discontinue participation.

WHAT IS INVOLVED IN THE STUDY?

At your first study visit you will:

1. Be randomized into one of two groups.
 - a. One group will be trained to remove their own drains at home.
 - b. The other group will have their drains removed by a provider at the standard of care clinic visit.
2. Both groups will be asked to complete a survey prior to receiving any training about their confidence in removing drains.
3. The group randomized to remove their drains will watch a video training, practice training on a model and be asked to complete a post-training survey and a satisfaction survey after self-removing their drain.

You will be randomized into one of the study groups described below. Randomization means that you are put into a group by chance. It is like flipping a coin.

Steps in the study:	Control Group Event	Intervention Group Event
Step 1	You will sign the ICF to participate in the study	You will sign the ICF to participate in the study
Step 2	You will be randomized in 1 of 2 groups	You will be randomized in 1 of 2 groups
Step 3	You will complete the pre-training survey	You will complete the pre-training survey
Step 4		You will be trained on how to remove your drain via video and model training
Step 5		You will complete the post-training survey
Step 6	Your drain will be removed	You will remove your drain

Page 2 of 9
Adult Consent Form

Version: 1
Date: 07/01/2024

WFU School of Medicine
Institutional Review Board
IRB Number:IRB00100883
Meeting Date Approved 7/17/2024
Version Valid Until: 7/16/2025

	at your post-operative clinic visit by a provider	at home without having to return to clinic
Step 7		You will complete a post self-drain removing survey
Step 8	Your outcomes will be tracked after drain removal for 30-days	Your outcomes will be tracked after drain removal for 30-days

If you take part in this study, you will have the following tests and procedures:

You will have a ventral hernia repair regardless of whether you participate in the study or not. If you choose to participate in the study, you may remove your own drains following your ventral hernia repair depending on the group you are randomized to. No other procedures performed, other than drain removal, will be different than the normal standard of care following a ventral hernia repair.

We can send copies of your test results to your personal physician. Even if you do not wish to have any of your medical information sent to your physician, you can still participate in this research study.

Do you request that we send important medical findings from your study tests/exams to your personal physician?

Yes No _____ Initials

HOW LONG WILL I BE IN THE STUDY?

You will be in the study for about 30-days.

You can stop participating at any time. If you decide to stop participating in the study, we encourage you to talk to the investigators or study staff first.

WHAT ARE THE RISKS OF THE STUDY?

Being in this study involves some risk to you. You should discuss the risk of being in this study with the study staff. Risks and side effects related to the procedure we are studying include:

More than Minimal Risk	This research involves more than minimal risk to subjects and the risk(s) represent a minor increase over minimal risk. You should discuss the risk of being in this study with the study staff.
Pain	The risk of pain from subjects pulling their own drain could involve a small amount of

	pain but this is not expected to be the case for most subjects.
Confidentiality and privacy	Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe.

There also may be other risks that we cannot predict. You should tell the research staff about all the medications, vitamins and supplements you take and any medical conditions you have. This may help avoid side effects, interactions and other risks to your health.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may or may not be direct benefit to you. We hope the information learned from this study will benefit other people in the future. The benefits of participating in this study may be: time, travel and cost savings associated with not having to return to clinic to have your drain removed. Because individuals respond differently to therapy, no one can know in advance if it will be helpful in your particular case.

WHAT OTHER CHOICES ARE THERE?

You do not have to be in this study. You should talk to the researchers about all the choices you have. Instead of being in this study, you have these options:

This is not a treatment study. Your alternative is to not participate in this study.

WHAT ARE THE COSTS?

All study costs, including any study products or procedures related directly to the study, will be paid for by the study. Costs for your regular medical care, which are not related to this study, will be your own responsibility.

WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required or permitted by law, or necessary to protect the safety of yourself or others.

Your information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

EMAIL COMMUNICATION. By providing my email address, I give permission for Atrium Health, Wake Forest University Health Sciences, and their respective affiliated entities and

Page 4 of 9
Adult Consent Form

Version: 1
Date: 07/01/2024

WFU School of Medicine
Institutional Review Board
IRB Number:IRB00100883
Meeting Date Approved 7/17/2024
Version Valid Until: 7/16/2025

representatives (including third-party agents if applicable) to send me information, reminders, and messages about the research study by email. I understand that these email messages may not be encrypted, and I understand and accept the risks that individuals not involved in the research study may be able to access unencrypted email messages. I also understand that email is not to be used for emergency situations.

WILL YOU BE PAID FOR PARTICIPATING?

You will receive no payment or other compensation for taking part in this study.

The findings from this research may result in the future development of products that are of commercial value. There are no plans to provide you with financial compensation or for you to share in any profits if this should occur.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by Atrium Health. The sponsor is providing money or other support to the researchers to help conduct this study. The researchers do not, however, hold a direct financial interest in the sponsor or the product being studied.

WHAT HAPPENS IF YOU EXPERIENCE AN INJURY OR ILLNESS AS A RESULT OF PARTICIPATING IN THIS STUDY?

Wake Forest University Baptist Medical Center maintains limited research insurance coverage for the usual and customary medical fees for reasonable and necessary treatment of injuries or illnesses to some participants in certain research studies. To the extent research insurance coverage is available under this policy, the reasonable costs of these necessary medical services will be paid, up to a maximum of \$25,000. To the extent research coverage is not available, you or your insurance company may be charged for the costs of medical care. You may receive care at Wake Forest University Baptist Medical Center and/or Atrium Health.

If you are injured, the insurer may require information such as your name, social security number, and date of birth in order to pay for your care. This is because the insurer is required by law to report any payments made to cover the care of any persons who are members of a government insurance plan to the Department of Health and Human Services.

You do not give up any legal rights as a research participant by signing this consent form. For more information on medical treatment for research related injuries or to report a study related illness, adverse event, or injury you should call Todd Heniford, MD at [REDACTED]

WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any new information we collect from you and/or information we get from your medical records or other facilities about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes:

1. Demographic information, including zip code

Page 5 of 9
Adult Consent Form

2. Comorbidities
3. Operative characteristics
4. Post-operative outcomes
5. Hospital charge data

If this research study involves the diagnosis or treatment of a medical condition, then Protected Health Information collected from you during this study will be placed in your medical record, and may be used to help treat you, arrange payment for your care, or assist with the health care operations of Atrium Health, Wake Forest University Health Sciences, and their respective affiliated entities.

We will take steps to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer.

Your personal health information and information that identifies you (“your health information”) may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.

Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; the Institutional Review Board; representatives of Wake Forest University Health Sciences and Atrium Health Facilities; representatives from government agencies such as the Food and Drug Administration (FDA) or the Office of Human Research Protections (OHRP), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study unless there are photographs or recorded media which are identifiable.

Monitors, auditors, IRB or other regulatory agencies will be granted direct access to your medical record for verification of clinical trial procedures or data to the extent permitted by other applicable laws. These monitors, auditors, and other individuals are also required to maintain the confidentiality of your protected health information.

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups, it may no longer be protected by federal or state

Page 6 of 9
Adult Consent Form

Version: 1
Date: 07/01/2024

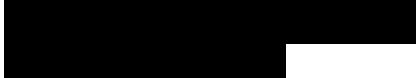
WFU School of Medicine
Institutional Review Board
IRB Number:IRB00100883
Meeting Date Approved 7/17/2024
Version Valid Until: 7/16/2025

privacy rules.

Any Protected Health Information collected from you in this study that is maintained in the research records any research information entered into your medical record will be kept for as long as your medical record is kept by the Medical Center. You will not be able to obtain a copy of your Protected Health Information in the research records until all activities in the study are completely finished.

You can tell Todd Heniford that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

Todd Heniford, MD



However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form you give us permission to use your Protected Health Information for this study.

If you choose to participate in this study, your medical record at Atrium Health, Wake Forest University Health Sciences, or their respective affiliated entities will indicate that you are enrolled in a clinical trial. Information about the research and any medications or devices you are being given as a participant may also be included in your medical record. Authorization to access this part of the medical record will only be available to people who have a need to know this information in order to perform their job-related duties. If you are not a patient of these health care facilities, a medical record will be created for you anyway to provide access to this important information to providers in case of an emergency.

A description of this clinical trial will be available on <http://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.

Laboratory test results and other clinically relevant medical reports created as a result of your participation in the research study may be entered into the computer systems of Atrium Health, Wake Forest University Health Sciences, and/or their respective affiliated entities. These results and reports will be kept secure in compliance with applicable laws, with permission to access this information limited to individuals with proper authority, but who may not be directly involved with this research study.

Page 7 of 9
Adult Consent Form

Version: 1
Date: 07/01/2024

WFU School of Medicine
Institutional Review Board
IRB Number:IRB00100883
Meeting Date Approved 7/17/2024
Version Valid Until: 7/16/2025

A medical record will be created for all study participants seen on-site and if a medical record doesn't already exist. Information about your participation in the study will be placed in the medical record, along with any routine medical test results that were obtained as part of this study.

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. This could be because it is in your best medical interest, your condition worsened, new information becomes available, you had an unexpected reaction, you failed to follow instructions, or because the entire study has been stopped. Information that identifies you may be removed from the data or specimens that are collected as part of this study and could be used for future research or shared with others without additional consent.

You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or in the event of a research-related injury, contact the study investigator, Todd Heniford, MD at [REDACTED]

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at [REDACTED] or the Research Subject Advocate at [REDACTED].

You will be given a copy of this signed consent form.

SIGNATURES

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Subject Name (Printed): _____

Page 8 of 9
Adult Consent Form

Version: 1
Date: 07/01/2024

WFU School of Medicine
Institutional Review Board
IRB Number:IRB00100883
Meeting Date Approved 7/17/2024
Version Valid Until: 7/16/2025

Subject Signature: _____ Date: _____ Time: _____ am pm

Person Obtaining Consent (Printed): _____

Person Obtaining Consent: _____ Date: _____ Time: _____ am pm

Legally Authorized Representative Name (Print): _____

The above named Legally Authorized Representative has legal authority to act for the research subject based upon (specify health care power of attorney, spouse, parent, etc.)

Relationship to the Subject: _____

Legal Representative Signature: _____ Date: _____ Time: _____ am pm

Page 9 of 9
Adult Consent Form

Version: 1
Date: 07/01/2024

WFU School of Medicine
Institutional Review Board
IRB Number:IRB00100883
Meeting Date Approved 7/17/2024
Version Valid Until: 7/16/2025