Wet-to-dry vs Petrolatum & Non-stick Dressings After Hidradenitis Suppurativa Surgery

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University of North Carolina at Chapel Hill
Consent to Participate in a Research Study
Adult Participants

Consent Form Version Date: 2/4/2022

IRB Study # 21-1989
Title of Study: Comparison of wet-to-dry vs petrolatum and non-stick dressing for second intention healing following hidradenitis suppurativa surgery
Principal Investigator: Chris Sayed
Principal Investigator Department: Dermatology - Adult
Principal Investigator Phone number: 919-450-7512
Principal Investigator Email Address: christopher_sayed@med.unc.edu

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CONCISE SUMMARY

Hidradenitis suppurativa (HS) is often treated with surgery, which can result in open wounds. Some surgeons prefer different methods for healing these wounds based on their experiences and beliefs about what results and the fastest and safest healing. This study hopes to answer whether one of two types of standard wound dressing techniques is superior to the other and associated with fewer drawbacks, such as pain related to and time dedicated to dressing changes.

Risks of participation include distress in anticipation of post-operative wound management, pain and discomfort following the procedure and with dressing changes, and infection. However, these risks accompany normal clinical unroofing procedures. There is always a risk of confidentiality breaches, but we will be mindful and attempt to minimize this risk at all times. In terms of potential direct benefits from your participation, one is that you will receive additional monitoring compared to a normal clinic patient due to follow up surveys and visits, which could help identify infections sooner.

To participate, you must be ≥16 years old, have undergone a surgical deroofing or excisional procedure that leaves an open wound, and must be able to perform wound care at home either individually or with the assistance of another individual.

What are some general things you should know about research studies?

You are being asked to take part in a research study. To join the study is voluntary.

You may choose not to participate, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies. Deciding not to be in the study or leaving the

study before it is done will not affect your relationship with the researcher, your health care provider, or the University of North Carolina-Chapel Hill. If you are a patient with an illness, you do not have to be in the research study in order to receive health care.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study.

You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?
The purpose of this research study is to determine whether there are any significant differences in wound healing, quality of life, and pain related to bandaging in two different types of post-surgical bandages.

Are there any reasons you should not be in this study?
You should not be in this study if your surgical wound was closed with sutures or staples.

How many people will take part in this study?
Approximately 100 patients here at UNC will take part in this study.

How long will your part in this study last?
You will be actively involved in this study for a minimum of 4 weeks and up to a maximum of 12 weeks.

What will happen if you take part in the study?
On the day of your surgery, you will be assessed for study eligibility by the principal investigator, Dr. Sayed. After surgery, Dr. Sayed will measure your wound and take an initial photograph. He will then exit the exam room. You will be randomly assigned to one of the two bandaging methods by a research assistant. The group to which you are assigned is entirely by chance, such as flipping a coin and getting heads or tails. Nurses will be provided the randomly assigned wound dressing materials by the research assistant. Nurses will help dress your surgical wound, instructing you on the process along the way. A printed instructional sheet specific to the assigned dressing technique will also be given to you for home reference. You will also be given disposable rulers and a small sample of wound dressing supplies. A wound check two weeks after your surgery day will be scheduled for you before you leave clinic, and/or we will describe procedures for measuring your wound and submitting photographs through the UNC MyChart portal.

You will be instructed to expect receipt of a virtual RedCap questionnaire via electronic mail or the UNC Epic MyChart account one week after your surgery. The questionnaire will once again be completed at your two-week in-person wound check. If you cannot make this appointment or are unable to attend an in-person wound check, a virtual questionnaire will be sent. Questionnaires will continue to be sent every 2 weeks until your wound has fully closed.

In addition to the questionnaire, you will also be asked to take photos of your wounds at weeks 1, 2, 4, and every two weeks until your wound is healed. You will send these photos to the research team via MyChart or electronic mail following a protocol you will be provided on the day of your surgery.

This study is partially blinded. This means that some of the people involved in this study will not know which bandaging technique you are using at home. The principal investigator, Dr. Sayed, will be blinded to the wound dressing technique you use as he will not be present for bandaging administration, but you as the patient will not be blinded as you will be administering the bandaging at home. Blinding of the evaluator, Dr. Sayed, is important because it limits any bias or preference he may have when evaluating your wounds and the results of the study. This also means that you should avoid discussing your bandaging technique when you come for your two-week wound check. However, if you have questions or any complications, instructions on who to contact will be included with your wound care instructions.

What are the possible benefits from being in this study?

Both wound dressing techniques are considered standard of care, so no matter which wound care you perform you are receiving standard of care. Research is designed to benefit society by gaining new knowledge. As we are investigating if any of the two bandaging techniques is superior, it is unknown how much you will personally benefit from being in this research study. There are no currently known direct benefits to you.

What are the possible risks or discomforts involved from being in this study?

There can be some distress in anticipation of post-operative wound management. We will do our best to gauge your comfort with doing at-home dressings and offer in-person training following the procedure as well as informational sheets describing proper steps for wound dressing for each of the two modalities being studied.

There is always a risk of confidentiality breaches, but we will be mindful and attempt to minimize this risk at all times. We will be storing all identifiable data on paper files that will be locked and secure in our clinic or maintained on a password protected UNC School of Medicine REDCap database online.

Pain and discomfort are very common following surgical deroofing procedures. Normal clinic protocol for post-operative pain management will be followed, which includes opioid and non-opioid analgesics depending on provider and patient preferences and needs. Pain with dressing changes can also occur, especially with wet-to-dry dressings. You will be informed of this risk during your dressing change postoperatively and during a bandage training session with the nurse. You will be instructed to contact the clinic in the event that dressing changes are too painful so that additional pharmacotherapy can be prescribed and other wound management strategies discussed. You will be made aware of these risks so that they have the opportunity to opt out of the bandaging protocol if needed.

There is a rare risk of infection with any surgical operation, including unroofing procedures. However, there is no known increased risk of infection for you if you decide to participate in this

study, as both bandaging types under investigation are used routinely in medical practice, with infection being a rare complication. You will be informed of infection risk prior to your procedure.

While not expected, there may be uncommon or previously unknown risks. You should report any problems to the researcher.

Are dressing supplies used in the study FDA-Regulated?

Each of the components of the dressings used in this study are approved by the FDA. However, the combination of the wound dressing products is not FDA-approved but is under investigation in this study.

If you choose not to be in the study, what other treatment options do you have?
You do not have to be in this research study in order to receive treatment. You will receive the same standard of treatment regardless of whether or not you participate in this study.

What if we learn about new findings or information during the study?
You will be given any new information gained during the course of the study that might affect your willingness to continue your participation.

How will information about you be protected?
Participants will not be identified in any report or publication about this study. We may use de-identified data and/or specimens from this study in future research without additional consent.

Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies (for example, the FDA) for purposes such as quality control or safety.

By signing this informed consent document, you agree that some of the information generated by participating in this study and/or a copy of the consent form may be included in your medical record and that this information may be viewed by other physicians or caregivers who provide healthcare services to you. This will allow the doctors caring for you to know what study medications or tests you may be receiving as a part of the study and know how to take care of you if you have other health problems or needs during the study. Additionally, the information may be shared with your medical insurance plan if the research services provided are billed to your insurance.

You will be asked to sign a separate form ("HIPAA Authorization") to allow researchers to review your medical records.

What will happen if you are injured by this research?
All research involves a chance that something bad might happen to you. If you are hurt, become

sick, or develop a reaction from something that was done as part of this study, the researcher will help you get medical care, but the University of North Carolina at Chapel Hill has not set aside funds to pay you for any such injuries, illnesses or reactions, or for the related medical care. Any costs for medical expenses will be billed to you or your insurance company. You may be responsible for any co-payments and your insurance may not cover the costs of study related injuries.

If you think you have been injured from taking part in this study, call the Principal Investigator at the phone number provided on this consent form. They will let you know what you should do.

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

What if you want to stop before your part in the study is complete?
You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have had an unexpected reaction, or have failed to follow instructions, or because the entire study has been stopped.

If you withdraw or are withdrawn from this study all data collected up until the point of withdrawal will be retained, however no additional information will be collected unless you provide additional written permission for further data collection at the time of your withdrawal.

Will you receive anything for being in this study?
You will not receive any monetary compensation for participation in this study. It is possible that some wound care materials will be provided immediately following your surgery to help you carry out your wound care as instructed.

Will it cost you anything to be in this study?
No. It will not cost anything extra to be in this study. However, you will be billed for your routine medical care. All tests, visits or procedures other than what is done for this study will be related to medical care that is part of the usual care for your condition. These would be suggested even if you decided not to be in the research study.

What if you have questions about this study?
You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

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 website at any time.

What if you have questions about your rights as a research participant?
All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you

would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

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Participant's Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

_____
Signature of Research Participant

_____
Date

_____
Printed Name of Research Participant

_____
Signature of Research Team Member Obtaining Consent

_____
Date

_____
Printed Name of Research Team Member Obtaining Consent

_____
Signature of Witness if applicable; e.g. literacy issues, visually impaired, physically unable to sign, witness/interpreter for non-English speaking participants using the short form)

_____
Date

_____
Printed Name of Witness