Official Title: Prospective case series on the use of methylene blue, gentian violet, and ovine forestomach-derived extracellular matrix wound dressings for Hidradenitis Suppurativa
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Wake Forest®
School of Medicine

Department of Dermatology

PROSPECTIVE CASE SERIES ON THE USE OF METHYLENE BLUE, GENTIAN VIOLET, AND OVINE FORESTOMACH-DERIVED EXTRACELLULAR MATRIX WOUND DRESSINGS FOR HIDRADENITIS SUPPURATIVA Informed Consent Form to Participate in Research

Rita O. Pichardo, MD, Principal Investigator

SUMMARY

You are invited to participate in a research study. The purpose of this research is to monitor the time it takes for wounds associated with Hidradenitis Suppurativa (HS) using Hydrofera Blue, Endoform, and Hypafix tape – wound care dressings. You are invited to be in this study because you have a diagnosis of HS. Your participation in this research will involve 5 visits and last about 2 months.

Participation in this study will involve using provided wound care dressings on non-healing, draining wounds that are due to HS. In addition to coming in for follow-up visits, you will be photographed at these visits to monitor wound healing. At each follow-up visit, you will complete questionnaires specific to the study and be provided with additional wound dressings. All research studies involve some risks. A risk to this study that you should be aware of is allergic reaction to the dressings. Additionally, you may experience site pain when applying or removing the dressings. There is the possibility that you may 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. There may be other choices available to you. Some other choices may include continuing with the standard of care for wounds, including gauze and tape. 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. The person in charge of this study is the Principal Investigator, Rita Pichardo, MD. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is: [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 Research Subject Advocate at Wake Forest at [redacted].

INTRODUCTION

You are invited to be in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You are being asked to take part in this study because you have Hidradenitis Suppurativa (HS)— a dermatological conditions that causes painful, draining nodules under the skin. Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate. 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 monitor healing time of wounds associated with HS using Endoform, Hydrofera Blue, and Hypafix tape, products that have been approved in the local management of external wounds by the US Food and Drug Administration (FDA).

Hydrofera Blue is an antibacterial foam dressing that contains methylene blue and gentian violet to manage wounds. This is a safe, non-cytotoxic product that can be worn for 7 days while not inhibiting growth factors. This product wicks bacteria into the foam and away from the wound surface using natural negative pressure through capillary flow.

Endoform is a natural dermal template used in all phases of wound healing. This product helps to stabilize, build, and organize tissue in acute and chronic wounds.

Hypafix tape aids in stabilization of wound dressings. It is easy to apply, skin friendly, and comfortable to use.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

10 people at 1 research site will take part in this study.

WHAT IS INVOLVED IN THE STUDY?

Participants with non-healing, draining open wounds due to HS will be eligible to participate in this study. After baseline/screening visit, participants will return at week 1, week 2, week 4, and week 8 for follow-up.

<u>Visits 1, 2, 3, 4, 5</u>

- Lesions will be photographed and measured
- Three wound care products will be provided to you: Endoform, Hydrofera Blue, and Hypafix tape. Amount of product will vary due to your wound size. Wound dressings are to be changed at least every 3 days.
- You will be provided with a standard cleansing regimen to follow for the duration of the study – please avoid using bleach baths or acidic products for the duration of the study
- Completion of Numerical Rating Scale of Pain
- Completion of the Dermatology Life Quality Index

- Completion of the Sartorius Hidradenitis Suppurativa Score – a standardized, objective scoring method that assesses disease severity by counting the number of lesions present along with their location on the body. This will be completed by study staff members.

As part of this research study, you will be photographed. This is being done to document wound healing. You understand that you may request the photographing be stopped at any time during the course of the research study. You can also withdraw your consent to use and disclose the photograph before it is used. You should also understand that you will not be able to inspect, review, or approve the photographs before they are used in this study.

Please choose one of the following regarding the use and disclosure of the photograph used in this research study:

_____ I would like the photographs of me to be destroyed once their use in this study is finished.

____ The photographs of me can be kept for use in future studies provided they are kept secure and any future study will be reviewed by an IRB. I understand that I will not be able to inspect, review or approve their future use.

HOW LONG WILL I BE IN THE STUDY?

You will be in the study for 2 months.

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 to learn about any potential health or safety consequences.

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 wound dressings we are studying include possible allergic reaction to the ingredients of the products. You may experience pain when applying or removing these products. There could be psychological effects from this study, due to pain associated with HS and quality of life impairment from HS. You could also experience infection due to the location of the lesions.

In addition, there is a slight risk of a breach of confidentiality. We will do our best to protect your confidential information. 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.

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.

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: wound healing and decreased pain due to non-healing wounds.

WHAT OTHER CHOICES ARE THERE?

You do not have to be in this study to receive treatment. You should talk to your doctor about all the choices you have. Instead of being in this study, you have these options: using the standard wound dressings of gauze and tape.

You could be treated with Endoform, Hydrofera Blue, and Hypafix products even if you do not take part in the study.

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

Should you experience a physical injury or illness as a direct result of your participation in this study, Wake Forest University School of Medicine maintains limited research insurance coverage for the usual and customary medical fees for reasonable and necessary treatment of such injuries or illnesses. 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. Wake Forest University Baptist Medical Center holds the insurance policy for this coverage. It provides a maximum of $25,000 coverage for each claim and is limited to a total of $250,000 for all claims in any one year. The Wake Forest University School of Medicine, and the North Carolina Baptist Hospitals, Incorporated do not assume responsibility to pay for these medical services or to provide any other compensation for such injury or illness. Additional information may be obtained from the Medical Center's Director of Risk and Insurance Management, at [redacted]

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 **Rita Pichardo, MD** at [redacted], or [redacted] (24 hours).

WHAT ARE THE COSTS?

All study costs, including any study medications and 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. Neither you nor your insurance company will be billed for the investigational device- Endoform, Hydrofera Blue and Hypafix tape.

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 by law, or necessary to protect the safety of yourself or others. There is always some risk that even de-identified information might be re-identified.

Participant 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.

The purpose of this research study is to obtain data or information on the safety and/or effectiveness of Hydrofera Blue, Endoform, and Hypafix tape – wound care products. The results will be provided to the sponsor, the Food and Drug Administration and other federal and regulatory agencies as required.

Photographs taken for this study will be stored in de-identified form in a password protected, institution computer.

WILL YOU BE PAID FOR PARTICIPATING?

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

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by the Department of Dermatology. Wound dressings are provided by Appulse Medical, suppliers of Endoform and Hydrofera Blue wound dressings and Hypafix tape. The sponsor is providing support to Wake Forest University Health Sciences to help conduct this study. The researchers do not, however, hold a direct financial interest in the sponsor or the product being studied.

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**:** medical history.

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 Medical Center operations.

We will make every effort 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 North Carolina Baptist Hospital; 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.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for at least six years after the study is finished. At that time any research information not already in your medical record will either be destroyed or it will be de-identified.

You can tell Rita Pichardo, MD 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:

Rita Pichardo, M.D.
[redacted]

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.

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, 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, Rita Pichardo, MD at [redacted] or [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):_____

Subject Signature: _____ Date: _____Time:_____ am pm

Person Obtaining Consent (Printed):_____

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