NCT Number:	NCT02805595
Official Title:	Effect of Sclerotherapy on Fistulas and Sinus Tracts in Hidradenitis Suppurativa
Document Type:	Informed Consent
Document Date:	10/23/2018

FOR CCI USE ONLY
Approved by the Beth Israel Deaconess Medical Center Committee on Clinical Investigations:

Consent Approval Date: 10/23/2018

Protocol Number: 2018P000600

BETH ISRAEL DEACONESS MEDICAL CENTER
APPROVED BY THE COMMITTEE ON CLINICAL INVESTIGATIONS
10/14/2019
APPROVAL EXPIRATION DATE

INFORMED CONSENT FORM TO TAKE PART IN A RESEARCH STUDY

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: A Single Center Clinical Trial to Evaluate the Effect of Sclerotherapy on Fistulas and Sinus Tracts in Adult Patients with Hidradenitis Suppurativa
PRINCIPAL INVESTIGATOR: Martina Porter, MD
PROTOCOL NUMBER: 2018P-000600

INTRODUCTION:

- This is a research study;
- Your participation is voluntary;
- A research study includes only people who choose to take part;
- You may or may not benefit from participating in the study. However, your participation may help others in the future as a result of knowledge gained from the research;
- You may leave the study at any time;
- If you choose not to take part, or if you leave the study, your decision will in no way harm your relationship with any member of the research team or any other individuals at Beth Israel Deaconess Medical Center.

Please read this consent form carefully and ask the investigators or study staff to explain any words or information that you do not clearly understand. Once you read this consent form and understand what your participation in this study will involve, you will be asked to sign this form if you wish to take part. You will be given a signed copy of the form to keep for your records.

DISCLOSURE OF SPECIAL INTERESTS OF BIDMC AND INVESTIGATORS

This study is being conducted by *Dr. Martina Porter* and is funded by the Hidradenitis Suppurativa Foundation. The funding agency in this study Hidradenitis Suppurativa Foundation is paying Beth Israel Deaconess Medical Center to perform this research. BIDMC or Dr. *Martina Porter* have *no* additional interests in this research project.

WHOM TO CONTACT IF YOU HAVE QUESTIONS OR PROBLEMS

If you have any questions, concerns or complaints about this research or experience any problems, you should contact Dr. Martina Porter at [617] 667-5834.

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: **A Single Center Clinical Trial to Evaluate the Effect of Sclerotherapy on Fistulas and Sinus Tracts in Adult Patients with Hidradenitis Suppurativa**
PRINCIPAL INVESTIGATOR'S NAME: **Martina Porter, MD**
PROTOCOL #: 2018P-000600

PURPOSE

We are doing this research study to see, whether injecting a concentrated salt solution (hypertonic saline) into the draining tunnels of hidradenitis suppurativa (HS) patients will make them stop draining. This same treatment is commonly used to treat varicose veins and is called sclerotherapy. We think it also may be effective for treating the draining tunnels.

Hypertonic saline involved in this study is investigational. This particular investigational agent (hypertonic saline) has been approved by the U.S. Food and Drug Administration (FDA) in low concentrations to treat dehydration but we do not yet known if it is useful or safe as a treatment to treat fistulas and sinus tracts in HS patients. Hypertonic saline is not approved by the FDA to treat fistulas and sinus tracts in HS patients.

STUDY PARTICIPANTS

You have been asked to be in the study *because you have HS with fistula(s)/sinus tracts.*

Approximately *20* people will take part in this study at Beth Israel Deaconess Medical Center.

DESCRIPTION OF STUDY DETAILS

If you agree to be in this study, you will be asked to read and sign this consent form. After you sign the consent form, the following things will happen:

Visit 1

This visit will take about 45 minutes. At this visit, we will:

- Test your urine for pregnancy, if you are a female able to become pregnant. Pregnant women can't take part in this research study.
- Take your medical history, including any medications you are currently taking or have taken in the past. You will need to tell the study doctor about all medications or therapies you have used for your HS in the past, even if you are not using them now.
- Examine and grade your HS.
- Ask you to fill out questionnaires about your HS and how it affects your life.
- Take photos of your HS.
- We will take pictures of your HS site.
- Perform ultrasound of your HS sites to determine presence of fistula(s). An ultrasound scan makes pictures of the body using sound waves. You will lie on a table. The operator will put a gel on your skin so the probe can make good contact. Then the operator will place the probe on your skin and will move it back and forth. The probe is like a hand-held microphone. The scan will take about 5-10 minutes.

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: **A Single Center Clinical Trial to Evaluate the Effect of Sclerotherapy on Fistulas and Sinus Tracts in Adult Patients with Hidradenitis Suppurativa**
PRINCIPAL INVESTIGATOR'S NAME: **Martina Porter, MD**
PROTOCOL #: 2018P-000600

- One site with fistula(s) is injected with Hypertonic Saline and ask you to fill out a pain/stinging questionnaire.

Visit 2 and 3:

This visit will take about 30 minutes. The visit will take place about 2 weeks after Visit 1. At this visit, we will:

- Test your urine for pregnancy
- Ask you about any changes in your health and medications since your last visit.
- Examine and grade your HS
- Ask you to fill out questionnaires about your HS and how it affects your life.
- Take photos of your HS.
- You'll receive another injection with Hypertonic Saline in the fistula(s) identified at first visit and ask you to fill out a pain/stinging questionnaire.
- Ask you and the physician to assess the treated areas.

Visit 4

This visit will take about 30 minutes. The visit will take place about 8 weeks after Visit 1. At this visit, we will:

- Ask you about any changes in your health and medications since your last visit.
- Examine and grade your HS
- Ask you to fill out questionnaires about your HS and how it affects your life.
- Take photos of your HS.
- Perform ultrasound of treated HS areas.
- Ask you and the physician to assess the treated areas.

After You Complete the Study

After you complete the study, we will refer you back to your own doctor for your ongoing medical care.

Stopping the Study Early

If you decide to stop taking part in the study for any reason, we will ask you to make a final study visit. The final study visit will take about 30 minutes. At this visit, we will:

- Examine and grade your HS
- Perform ultrasound of the treated areas
- Ask you about any side effects or health problems since your last visit
- Ask you to fill out some questionnaires

RISKS AND DISCOMFORTS

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: **A Single Center Clinical Trial to Evaluate the Effect of Sclerotherapy on Fistulas and Sinus Tracts in Adult Patients with Hidradenitis Suppurativa**
PRINCIPAL INVESTIGATOR'S NAME: **Martina Porter, MD**
PROTOCOL #: 2018P-000600

As a result of your participation in this study, you are at risk for side effects listed in this section. You should discuss these with the investigator and with your regular doctor if you choose.

More Common: The most common side effect is pain and/or stinging upon injection of the hypertonic saline into the fistula tract. It may last for a period of time after the procedure but this discomfort should then resolve on its own.

Less Common: While uncommon it is possible that the injection will result in Skin Ulceration. Ulceration is a side effect seen when sclerotherapy is used for varicose veins. The skin may become discolored and/or the top layer of the skin may break down. This can be treated with local wound care including bandaging the area and keeping it clean.

Rare: A rare side effect is that the injection could lead to Infection as this is a procedure that involves inserting a needle and medication (hypertonic saline) into the skin. We will take steps to minimize this risk including using sterile needles and cleaning the affected area with an alcohol wipe prior to the procedure.

There may be other risks of hypertonic saline that are currently unknown.

If you are pregnant or become pregnant, this treatment may involve risks to the embryo or fetus which are currently unforeseeable.

PREGNANCY

Because of the effects of this study medication on the developing fetus is not known, you may not participate in this study if you are pregnant. You will be required to take a pregnancy test to verify that you are not pregnant before receiving your first dose of the study medication.

For the duration of the study, if you are engaged in sexual activity that could cause you or your partner(s) to become pregnant, you and your partner(s) must agree to use a highly effective method of birth control or abstain from sexual activity that could cause you or your partner(s) to become pregnant

The methods of highly effective birth control for this study are below:

1. Contraceptive implant, such as Nexplanon or Implanon
2. Levonorgestrel or copper intrauterine device (IUD), such as Mirena, Skyla, ParaGard or Liletta
3. Permanent female sterilization, such as tubal ligation or Essure with confirmed tubal occlusion
4. Male partner(s) has had a vasectomy more than three months before study enrollment
5. Oral contraceptives pill, patch or ring
6. Injectable contraception, such as Depo Provera
7. Consistent use of a barrier method, such as diaphragm with spermicide or condoms

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: **A Single Center Clinical Trial to Evaluate the Effect of Sclerotherapy on Fistulas and Sinus Tracts in Adult Patients with Hidradenitis Suppurativa**
PRINCIPAL INVESTIGATOR'S NAME: **Martina Porter, MD**
PROTOCOL #: 2018P-000600

If you believe you have become pregnant while participating in this study, you must inform your study doctor immediately.

Other Risks Related to Study Procedures

ULTRASOUND
An ultrasound will be performed. There is no known radiation risks associated with standard ultrasound procedures. For this study the Philips Lumify Ultrasound Device will be used. You may experience mild pain from ultrasound examination of your lesions.

LOSS OF CONFIDENTIALITY
There is the potential for loss of confidentiality by participating in this study. Every effort will be made to protect the confidentiality of your identifiable information.

MEDICAL RECORD

A copy of this consent form and information collected during this research may become part of your medical record, if the information is relevant to the care you receive at Beth Israel Deaconess Medical Center. Medical records are considered permanent records; therefore, information cannot be deleted from the record. Medical records are available to health care professionals at Beth Israel Deaconess Medical Center and may be reviewed by staff when carrying out their responsibilities, as well as by external parties such as health care insurers and others in certain circumstances. If you are not currently a patient at Beth Israel Deaconess Medical Center and do not have a medical record at Beth Israel Deaconess Medical Center, one may be created for you for your participation in this research. You may also be required to register as a patient of Beth Israel Deaconess Medical Center in order to participate in this research.

POSSIBLE BENEFITS

It is not possible to predict whether you will benefit directly from participation in this study. However, your participation may help others in the future as a result of knowledge gained from the research.

OTHER AVAILABLE OPTIONS

Taking part in this study is voluntary. Instead of being in this study, you have the following options:

- Injection with intralesional steroids (kenalog)
- Surgical excision

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: **A Single Center Clinical Trial to Evaluate the Effect of Sclerotherapy on Fistulas and Sinus Tracts in Adult Patients with Hidradenitis Suppurativa**
PRINCIPAL INVESTIGATOR'S NAME: **Martina Porter, MD**
PROTOCOL #: 2018P-000600

Hypertonic Saline has not been approved by the FDA for treatment of your condition, however, many doctors in the community commonly prescribe the drug to treat varicose veins. Please be aware that not all doctors may agree to prescribe this drug for you, and that not all health insurance companies will pay for the drug when it is prescribed for varicose veins or hidradenitis suppurativa.

This research study is not meant to diagnose or treat medical problems. Participation in this research study does not take the place of routine physical examinations or visits to your regular doctor.

We recommend that you discuss these and other options with the investigator and your regular doctor so that you can make a well-informed decision about participating in this study.

IF YOU DECIDE NOT TO TAKE PART IN THE STUDY

Participation in this study is voluntary. You have the right to decide not to take part in this study. If you choose to participate, you have the right to leave the study at any time. Your decision to not participate will not result in any penalties or loss of benefits to you. The investigators will tell you about new information that may affect your willingness to stay in this study.

If you decide not to participate in the study or decide to leave the study early, your decision will not affect your relationship with the research team or any other individual at Beth Israel Deaconess Medical Center.

INVESTIGATORS RIGHT TO STOP THE STUDY

The investigators have the right to end your participation in this study if they determine that you no longer qualify to take part, or if it would be dangerous for you to continue, or if you do not follow study procedures as directed by the investigators. Beth Israel Deaconess Medical Center or the funding source may stop the study at any time.

COSTS AND/OR PAYMENTS TO YOU

COSTS COVERED BY STUDY

You will not be charged for *tests, procedures, medications* that are part of this research study.

PAYMENTS TO YOU:

It may take up to 8 weeks for you to receive payment by check.

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: **A Single Center Clinical Trial to Evaluate the Effect of Sclerotherapy on Fistulas and Sinus Tracts in Adult Patients with Hidradenitis Suppurativa**
PRINCIPAL INVESTIGATOR'S NAME: **Martina Porter, MD**
PROTOCOL #: 2018P-000600

Any payments made to you may be taxable income to you. This does not include any payments you may receive to reimburse (pay you back) you for certain expenses like parking fees or travel. We are required to obtain your name and social security number for preparation and submission of Internal Revenue Service (IRS) Form 1099-Misc. You may receive an Internal Revenue Service Form 1099 from BIDMC if you receive more than $600 or more in one calendar year for taking part in one or more research studies at BIDMC. Questions about your own tax status should be referred to your personal tax advisor.

You will be paid for the following: *$25 per study visit if you qualify for the study.*

COST OF RESEARCH RELATED INJURY:

If you are injured as a direct result of your participation in this study you should contact the Investigator at the number provided under the section "Whom to Call if You Have Questions" in this form. You will be offered the necessary care to treat your injury. You or your insurance company will be billed for medical care and/or hospitalization related to this injury. You will be responsible for all co-payments and deductibles required under your insurance. BIDMC will consider reimbursement of injury related expenses not covered by your insurance on a case-by-case basis. At this time there is no plan to reimburse you for items such as lost wages or lost time from work. By signing this consent form you have not given up any legal rights.

OTHER IMPORTANT INFORMATION

A description of this clinical trial will be available on www.ClinicalTrials.gov as required by U.S. law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

AUTHORIZATION FOR USE AND DISCLOSURE OF YOUR PROTECTED HEALTH INFORMATION

As part of this study, we will be collecting, using and sharing with others information about you. Please review this section carefully as it contains information about the federal privacy rules and the use and disclosure of your information.

PROTECTED HEALTH INFORMATION [PHI]

By signing this informed consent document, you are allowing the investigators and other authorized personnel to use [internally at BIDMC] and disclose [to people and organizations outside the BIDMC workforce identified in this consent] health information about you. This may include information about you that already exists (for example: your medical records and other sources of health information, demographic information, the results of any laboratory tests, and mental health records

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: **A Single Center Clinical Trial to Evaluate the Effect of Sclerotherapy on Fistulas and Sinus Tracts in Adult Patients with Hidradenitis Suppurativa**
PRINCIPAL INVESTIGATOR'S NAME: **Martina Porter, MD**
PROTOCOL #: 2018P-000600

if applicable as well as any new information generated as part of this study. This is your Protected Health Information.

PEOPLE/GROUPS AT BIDMC WHO WILL SHARE AND USE YOUR PROTECTED HEALTH INFORMATION

Your Protected Health Information may be shared with and used by investigators working on this study, including the supporting research team (such as research assistants and coordinators, statisticians, data managers, laboratory personnel, pharmacy personnel, and administrative assistants), and may also be shared and used by other health care providers at BIDMC who have treated you in the past and have information relevant to the research, or who provide services to you in connection with the research. Your Protected Health Information may also be shared with the members and staff of the Committee on Clinical Investigations of Beth Israel Deaconess Medical Center, which is responsible for reviewing studies for the protection of the research subjects.

PEOPLE/GROUPS OUTSIDE OF BIDMC WITH WHOM YOUR PROTECTED HEALTH INFORMATION WILL BE SHARED

We will take care to maintain confidentiality and privacy about you and your Protected Health Information. We may share your Protected Health Information with the following groups so that they may carry out their duties related to this study:

- The other hospitals and medical centers taking part in this study and research collaborators at those institutions
- Any external health care providers who provide services to you in connection with this research
- Laboratories not affiliated with BIDMC that are involved in conducting tests related to the research
- Statisticians and other data monitors not affiliated with BIDMC
- The members and staff of any other IRBs (beyond the BIDMC Committee on Clinical Investigations) that oversee the research
- Centralized data collectors
- Your health insurance company
- The Food and Drug Administration [FDA], the Department of Health and Human Services [DHHS], the National Institute of Health [NIH], the Office for Human Research Protections [OHRP], and other federal and state agencies that may have jurisdiction over the research
- Hospital and Clinical Research Accrediting Agencies
- Data and Safety Monitoring boards that oversee this study (if applicable)

Those who receive your Protected Health Information during the course of the research may not be required by the federal privacy regulations to protect it, and they may make further disclosures to others and use your information without being subject to penalties under those laws.

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: **A Single Center Clinical Trial to Evaluate the Effect of Sclerotherapy on Fistulas and Sinus Tracts in Adult Patients with Hidradenitis Suppurativa**
PRINCIPAL INVESTIGATOR'S NAME: **Martina Porter, MD**
PROTOCOL #: 2018P-000600

WHY WE ARE USING AND SHARING YOUR PROTECTED HEALTH INFORMATION

The main reason for using and sharing your Protected Health Information is to conduct and oversee the research as described in this Informed Consent Document. There are many other reasons beyond the research for which BIDMC may use or disclose your Protected Health Information. Not all of these reasons require your express written authorization. For example, we will use and share your Protected Health Information to ensure that the research meets legal, institutional and accreditation requirements and to conduct public health activities. The various ways in which BIDMC may use and disclose your protected health information without your authorization are explained in a document called the Notice of Privacy Practices. If you have not received a copy of BIDMC's Notice of Privacy Practices, please ask us for one and review it before signing this form. In addition to signing this document, you may also be asked to sign a BIDMC General Agreement form acknowledging that you have received the BIDMC Notice of Privacy Practices.

NO EXPIRATION DATE – RIGHT TO WITHDRAW AUTHORIZATION

Your authorization for the use and disclosure of your Protected Health Information in this Study shall never expire. However, you may withdraw your authorization for the use and disclosure of your Protected Health Information at any time provided you notify the Principal Investigator in writing. If you would like to take back your authorization so that your Protected Health Information can no longer be used in this study, please send a letter notifying the Principal Investigator of your withdrawal of your authorization to Dr. Martina Porter at 330 Brookline Ave., Boston, MA 02215. Please be aware that the investigators in this study will not be required to destroy or retrieve any of your Protected Health Information that has already been used or disclosed before the Principal Investigator receives your letter, and they are permitted to continue to use and disclose your previously collected information as necessary to complete the research.

REFUSAL TO SIGN

Your clinical treatment may not be conditioned upon whether you sign the Authorization for Research. However, if you choose not to sign this informed consent document and authorization for the use and disclosure of your Protected Health Information, you will not be allowed to take part in the research study.

RIGHT TO ACCESS AND COPY YOUR PHI

If you wish to review or copy your Protected Health Information as it is made part of your medical record, you may do so after the completion or termination of the study by sending a letter to the Principal Investigator requesting a copy of your Protected Health Information. You may not be allowed to inspect or copy your Protected Health Information until this study is completed or terminated.

ADDITIONAL CONTACT FOR QUESTIONS OR CONCERNS

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: **A Single Center Clinical Trial to Evaluate the Effect of Sclerotherapy on Fistulas and Sinus Tracts in Adult Patients with Hidradenitis Suppurativa**
PRINCIPAL INVESTIGATOR'S NAME: **Martina Porter, MD**
PROTOCOL #: 2018P-000600

You may contact the Human Subjects Protection Office at [617] 975-8500 in the event that you would like to obtain information or to offer input about the research study. This office is independent of the investigator or investigator's research staff and can also assist with questions relating to your rights as a participant in research, which may include questions, concerns or complaints about your participation in the study.

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: **A Single Center Clinical Trial to Evaluate the Effect of Sclerotherapy on Fistulas and Sinus Tracts in Adult Patients with Hidradenitis Suppurativa**
PRINCIPAL INVESTIGATOR'S NAME: **Martina Porter, MD**
PROTOCOL #: 2018P-000600

BETH ISRAEL DEACONESS MEDICAL CENTER
APPROVED BY THE
COMMITTEE ON CLINICAL INVESTIGATIONS
10/14/2019
APPROVAL EXPIRATION DATE

THE FOLLOWING PARAGRAPHS CONTAIN SOME STANDARD INFORMATION WHICH GENERALLY APPLIES TO INDIVIDUALS PARTICIPATING IN A RESEARCH STUDY.

CONSENT FORM FOR CLINICAL RESEARCH

I have read the previous page[s] of the consent form and the investigator has explained the details of the study. I understand that I am free to ask additional questions.

If I wish additional information regarding this research and my rights as a research subject, or if I believe I have been harmed by this study, I may contact the Human Subjects Protection Office (HSPO).

I am aware that this is a research project and that unforeseen side effects may occur.

I understand that the Beth Israel Deaconess Medical Center has no formal program for compensating patients for medical injuries arising from this research. Medical treatment will be provided for injuries at the usual charge to me or to my insurer unless payment is otherwise provided for in this consent form.

I understand that participation in this study is voluntary and I may refuse to participate or may discontinue participation at any time without penalty, loss of benefits, or prejudice to the quality of care which I will receive.

I acknowledge that no guarantees have been made to me regarding the results of the treatment involved in this study, and I consent to participate in the study and have been given a copy of this form.

_____ _____

Signature of Subject or Legally Authorized Representative (Parent if the subject is a minor) — Date

_____

Relationship of Legally Authorized Representative to Subject

The subject has been given the opportunity to read this consent form and to ask questions before signing, and has been given a copy.

_____

SIGNATURE OF INVESTIGATOR/Co-Investigator DATE

_____

PRINT INVESTIGATOR'S/Co-Investigator's NAME

A signing co-investigator must be listed on the study's approved Research Staffing Form at the time of consent.