

Hydroxychloroquine for the Treatment of Hidradenitis Suppurativa

NCT #: n/a

09/01/2017

Consent to Act as a Participant in a Research Study

STUDY TITLE: Pilot Study of Hydroxychloroquine for the Treatment of Hidradenitis Suppurativa

PRINCIPAL INVESTIGATOR: Elena Gonzalez Brant, MD. Phone (412) 647-4200

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QUESTIONS ABOUT THE STUDY:

If you have any questions about your rights as a research subject or wish to talk to someone other than the research team, please call the University of Pittsburgh Human Subjects Protection Advocate toll-free at 866-212-2668.

You can contact the study investigator if you have any questions about the study, concerns or complaints. Contact Principal Investigator, Dr. Gonzalez Brant at (412) 647-4200.

INTRODUCTION:

Hidradenitis suppurativa (HS) is an under-recognized and debilitating disease. Patients suffer from recurring painful abscesses and scarring in their armpits, under the breasts, groin and other areas of the body. The cause of the disease is still unknown and common treatments are only sometimes effective. Current therapies have long-term risks including antibiotic resistance and we aim to find new safe and effective therapies for HS. We believe that hydroxychloroquine has the potential to improve HS through multiple mechanisms.

Overactivity of the immune system has been associated with HS and molecules that cause inflammation have been found in the skin from people with HS. We aim to look at the blood of patients with HS to look for inflammatory molecules that we could possibly target for the treatment of HS.

Patients with mild-to-moderate HS are being asked to participate. We hope to find 20 subjects to be involved in this study.

You will be enrolled in the study for approximately 13 months

PURPOSE OF THE STUDY:

We aim to see if hydroxychloroquine is a safe and reasonable treatment for hidradenitis suppurativa. We also want to see if the levels of inflammatory molecules are different in the blood of people with HS compared to people without HS.

WHEN THE INVESTIGATOR IS ALSO THE CARE-PROVIDER:

Your physician is involved as an investigator in this research study. Before agreeing to participate, or at any time during your study participation, you may discuss your care with another doctor who is not associated with this research study. You are not under any obligation to participate in any research study offered by your physician.

RESEARCH ACTIVITIES:

1. Screening Procedures

- Before you can be enrolled in this study, we will need to do some blood tests to make sure your liver function, kidney function and blood counts are within the normal range
- If you are a woman of child-bearing potential we will perform a pregnancy test because this medication should not be used during pregnancy

2. Treatment with hydroxychloroquine

- Hydroxychloroquine is an oral medication (pill) that has been used safely to treat a variety of diseases since 1955. It is FDA approved for the treatment of lupus, rheumatoid arthritis and malaria. Hydroxychloroquine is not FDA approved for the treatment of HS.
- You will be asked to take a 200mg pill two times a day for 6 months.
- It is recommended that you use sunscreen, as this medication can cause photosensitivity
- You will be evaluated for any side effects with a telephone call after 1 month and at your 3 and 6 month follow up visits.
- If you experience any side effects while on this medication, you will be instructed to contact your doctor to let them know
- If you have good results with this treatment, you may be able to continue the treatment after the study is completed
- You may continue to use medicated washes, creams, ointments and lotions during this study
- You will be evaluated for any side effects with a telephone call 3 and 6 months after your finish your treatment.
- You will be asked to have a baseline eye exam within the first year of treatment

3. *Optional* collection of blood samples for analysis of markers of inflammation

- Inflammation is known to drive HS, but the mechanism it is still not well understood in this disease. If we can understand more about the inflammatory molecules in HS, we can potentially identify new treatments.
- If you would like to provide a blood sample, a small sample of your blood will be taken at the beginning of the study and after you have had 6 months of treatment
- Your blood samples will be stored without your name or other identifying information
- **You may still participate in this study if you choose not to provide blood samples**

4. Quality of life questionnaire

- You will be asked to complete a short paper questionnaire about your quality of life before you start treatment and at your 3 and 6 month follow up appointments. It should not take longer than 15 minutes to complete each time.

STUDY RISKS:

- The use of hydroxychloroquine has been evaluated in many other diseases and is quite safe. Side effects include blurred vision, changes in vision, dizziness, headache, abdominal pain, nausea, vomiting, diarrhea, itching, and low appetite. **You should not take this medication if you are pregnant or are planning to become pregnant.** Rare

side effects include imbalance, hair bleaching, sun sensitivity, ringing in the ears, low blood counts, seizures, lip and throat swelling, trouble breathing, skin rashes, worsening of psoriasis, worsening of porphyria (a light-sensitive skin condition), eye disease, heart disease, liver disease, heart rhythm abnormalities, depression, psychosis, anxiety, suicidality, low blood sugar.

- Getting your blood drawn will be no different than you have experienced for other lab testing. There is a very low risk of infection at the site of the blood draw. Bruising may occur at the site of the blood draw.

STUDY BENEFITS:

- Thorough screening and side effect monitoring will be used to minimize risk during treatment with hydroxychloroquine.
- Participation in this study may help to **improve your HS**

ALTERNATIVE TREATMENTS:

- Other possible treatment options include medicated washes, antibiotic creams, oral antibiotics (including doxycycline, clindamycin and rifampin), acitretin, isotretinoin, biologic medications (adalimumab), corticosteroids, hormone manipulation and surgical intervention
- If you would like to discuss any alternative treatments to this research study, your doctor will be available to do so.
- If you do not want to participate in the research study, you may still be able to get treatment with hydroxychloroquine, if you choose to do so

NEW INFORMATION:

You will be promptly notified if any new information we learn during this research study may cause you to change your mind about continuing to participate in the study.

PRIVACY (Person) and CONFIDENTIALITY (Data):

- Your identification will be removed from the research data. Linkage code information will be stored in a separate locked cabinet
- Only the principal investigator (Dr. Gonzalez Brant) and co-investigator (Dr. Akilov) will have access to your data
- Per University of Pittsburgh policy all research records must be maintained for at least 7 years following final reporting or publication of a project.

SUBJECT ACCESS TO RESEARCH RESULTS IN MEDICAL RECORDS :

- This research study will involve the review of your medical records to confirm your eligibility to participate in this study.
- You will be provided with the final results of the study once the study has been completed (all 20 participants have completed 6 months of treatment). These results will be sent to you by mail.

FDA Clinical Trial Registry

A description of this clinical trial will be available on <http://www.clinicaltrials.gov>, as required by US 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.

WITHDRAWAL FROM STUDY PARTICIPATION:

1. You can, at any time withdraw from this research study; you can also withdraw your authorization for us to use your identifiable medical information for the purposes described above. This means that you will also be withdrawn from further participation in this research study. Any identifiable research or medical information obtained as part of this study prior to the date that you withdrew your consent will continue to be used and disclosed by the investigators for the purposes described above.
2. To formally withdraw from this research study, you should provide a written and dated notice of this decision to the principal investigator of this research study at the address listed on the first page of this form. Your decision to withdraw from this study will have no effect on your current or future relationship with the University of Pittsburgh.
3. Your decision to withdraw your consent for participation in this research study will have no effect on your current or future medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider.
4. Investigator removes subject from study:
 1. It is possible that you may be removed from the research study by the researchers if, for example, you are having an adverse reaction to the drug
5. Investigator may request follow-up for safety reasons: If you are withdrawn from participation in this research study, you will be asked to continue to follow up to ensure resolution of any adverse reaction

COSTS:

- **The cost of the drug is not covered by the research study** and you or your insurer will be responsible for covering this cost. The cost of the lab testing will be paid for by the research study. You will be charged in the usual manner for any procedures performed as part of your standard medical care (care you would receive even if you were not participating in this research study).

COMPENSATION FOR INJURY:

- If you believe that the research procedures have resulted in an injury to you, immediately contact the Principal Investigator who is listed on the first page of this form. Emergency

medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC. Your insurance provider may be billed for the costs of this emergency treatment, but none of those costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care. At this time, there is no plan for any additional financial compensation. You do not, however, waive any legal rights by signing this form.

VOLUNTARY PARTICIPATION:

Your participation in this research study is entirely voluntary. You may want to discuss this study with your family and friends and your personal physician before agreeing to participate. If there are any words you do not understand, feel free to ask us. The investigators will be available to answer your current and future questions.

Whether or not you provide your consent for participation in this research study will have no effect on your current or future relationship with the University of Pittsburgh. Whether or not you provide your consent for participation in this research study will have no effect on your current or future medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider.

As both your doctor and a research investigator, she is interested both in your medical care and the conduct of this research study. Before agreeing to participate in this research study, or at any time during your study participation, you may discuss your care with another doctor who is not associated with this research study. You are not under any obligation to participate in any research study offered by your doctor.

To formally withdraw your consent for participation in this research study you should provide a written and dated notice of this decision to the principal investigator of this research study at the address listed on the first page of this form.

VOLUNTARY CONSENT:

The above information has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions, voice concerns or complaints about any aspect of this research study during the course of this study, and that such future questions, concerns or complaints will be answered by a qualified individual or by the investigator(s) listed on the first page of this consent document at the telephone number(s) given.

I understand that I may always request that my questions, concerns or complaints be addressed by a listed investigator. I understand that I may contact the Human Subjects Protection

Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations that occurred during my participation.

By signing this form I agree to participate in this research study and for the use and disclosure of my medical record information for the purposes described above. A copy of this consent form will be given to me.

Printed name of Participant

Signature of Participant

Date

CERTIFICATION OF INFORMED CONSENT

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions, concerns or complaints as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

Printed Name of Person Obtaining Consent

Role in Research Study

Signature of Person Obtaining Consent

Date