NCT04908280

CONSENT FORM

Title: Exploratory Study of Ruxolitinib Cream for the Treatment of Discoid Lupus Erythematosus

Principal Investigator: Christopher T. Richardson MD, PhD

Study Related Phone Numbers: 585-273-4195
585-275-7546 (24 hours)

This consent form describes a research study, what you may expect if you decide to take part and important information to help you make your decision. Please read this form carefully and ask questions about anything that is not clear before you agree to participate. You may take this consent form home to think about and discuss with family or friends.

Key Information

- Being in this study is voluntary – it is your choice.
- You are being asked to take part in this study because you have discoid lupus (DLE).
- The purpose of this study is to assess the potential beneficial effect of ruxolitinib cream for the treatment of DLE.
- Your participation in this study will last for about 16 weeks.
- Procedures will include treatment with ruxolitinib cream, clinical assessment of your response to treatment, photographs of your skin, blood draws, and optional skin biopsies.
- There are risks from participating. The most common risk is mild skin irritation from the creams. See the "Risks of Participation" section in this consent form for more information. You should discuss these risks in detail with the study team.
- You might not benefit from being in this research study. The potential benefits to you might be 1) more frequent provider evaluation and management of your skin disease, and 2) better control of your skin disease.
- If you do not want to take part in this study, you will receive routine care for your skin disease.

Purpose of Study

The purpose of this study is to assess the potential beneficial effect of ruxolitinib cream for the treatment of DLE. There are no creams specifically FDA-approved for use in lupus and a great need exists for new treatments. Ruxolitinib cream has been shown to be safe and effective in a number of other skin diseases such as eczema, but has not been studied in discoid lupus.

Description of Study Procedures

If you decide to take part in this study, you will be asked to apply ruxolitinib cream to your lupus skin lesions twice a day for 12 weeks. You will also be asked to visit the clinic a total of seven times for assessment of your treatment, as outlined below.

Standard of care for patients with DLE depends on their disease severity. Treatment for patients can include topical steroids, topical calcineurin inhibitors, systemic antimalarials, and systemic immunosuppressive medications. Participants in this sudy will replace any standard topical therapies they are using with ruxolitinib, the study drug. Participants may continue systemic antimalarials as standard of care during the study. There is no known risk of interaction between antimalarials and ruxolitinib. Systemic immunosuppression medication is not used as commonly as the other treatments for DLE. Patients using systemic immunosuppression medications will not be included in the study.

Visit 1: Screening Visit

At this visit, you will be asked to read this form. No procedures relating to the study will happen until you have given consent. If, after you have read this consent form and all of your questions have been answered, you would like to participate in this study, you will be asked to sign this consent form. We will then ask questions about your medical history, record your vital signs, complete a physical exam, and take a blood sample.

Visit 2: Treatment Initiation Visit

At this visit, your eligibility to take part in this study will be confirmed and you will be officially enrolled in the clinical trial. In addition, the following will occur during this visit:

- Vital signs and physical exam, including skin assessments
- Photographs of your skin
- Symptom Diary teaching
- Blood draw
- Tubes of cream will be provided.
- If you agree, an optional skin biopsy will be taken.

Visits 3-6 (at 2, 4, 8, and 12 weeks): Treatment Visits

The following will occur during these visits:

- Vital signs and physical exam, including skin assessments
- Review of side effects
- Photographs of your skin
- Symptom Diary review
- Blood draw (only Visits 4 and 12)

- Tubes of creams will be weighed, and new tubes provided if needed.
- Symptom Diary and leftover cream will be collected (only Visit 12).
- If you agree, an optional skin biopsy will be taken (only Visit 12).

Visit 7 (at 16 weeks): Follow-up Visit

Vital signs and a physical exam will be conducted. Side effects will be reviewed.

Unscheduled Visits

In the event that one of the activities listed above is not able to be completed during a regular study visit, your skin disease worsens, or you have other concerns, you may be asked to return to the clinic for an "unscheduled visit." During this unscheduled visit, any of the activities listed above may be performed.

Information about your study participation and study results may be included in your electronic health record. If you have concerns about this or to obtain more detail, you should discuss this with the study team.

Number of Subjects

Fifteen subjects will take part in this study.

Risks of Participation

A description of this clinical trial will be available on http://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 website at any time.

The study team may be notified if you receive other health care services at URMC or its Affiliates (e.g., visit to the emergency room). In addition, the following individuals may know you participated in research and may see results of testing conducted for this study:

- Staff at the University of Rochester Medical Center and its Affiliates (e.g., Strong Memorial Hospital, Highland Hospital, URMC primary care, specialist physician offices) who have a reason to access your electronic health record.
- Health care providers who are involved in your care at a facility that is not part of the University of Rochester Medical Center and its Affiliates and who have reason to access your electronic health record.

- Individuals who request a copy of information from your health record for activities such as treatment or payment (e.g., medical insurance companies, worker's compensation).

Ruxolitinib cream:
Skin-related side effects of ruxolitinib cream are rare, but have included local irritation, pain, itch, redness, acne, and rash. While other side effects are not expected and have not been seen in other studies of ruxolitinib cream, there is a potential risk of side effects that have been observed with much higher doses of ruxolitinib when given by mouth. These risks include infection, low blood counts, liver inflammation, elevated cholesterol, dizziness, headache, fatigue, insomnia, diarrhea, and abdominal pain. As with any treatment, there is a small risk of an allergic reaction, though this has not been documented for ruxolitinib cream.

There is a risk of no change or worsening of disease, as would be true with any change in treatment. There is no known risk of interaction between antimalarials and the study drug, ruxolitinib.

Blood draw:
The risks of having blood drawn include some pain with needle insertion and a small risk of bruising and/or infection at that site. Some people may get lightheaded, nauseated, or faint. Only a trained professional will perform this draw blood.

Biopsy (optional):
The skin punch biopsy procedure involves the momentary pain of the needle prick used to insert the local anesthetic. There is a low risk of having an allergic reaction to the anesthetic used (lidocaine with epinephrine), which could rarely result in a rash, itching, swelling, dizziness, or trouble breathing. There is also a low risk of skin discoloration, temporary bleeding/bruising, and infection. You may develop a small scar at the biopsy site. Only a trained professional will perform this biopsy.

Benefits of Participation

You might not benefit from being in this research study. The potential benefit to you from being in this study might be more frequent provider evaluation and management of your skin disease as well as potential efficacy of a new therapy.

Alternatives to Participation

Non-participation. Study participation is voluntary. You are free to not participate or to withdraw at any time, without risking loss of present or future care that they would otherwise receive.

Compensation for Injury

If you are directly injured by the drugs being studied, or by medical procedures needed because of this study, and you receive medical care for the injury, you may need to pay for that care. You will be reimbursed for reasonable and necessary medical costs for such care, but you might not be reimbursed for care covered and paid for by a third party like your health insurance provider, or costs such as required co-payments or deductibles related to that coverage. No other funds have been set aside to pay for such things as lost wages or expenses due to a current underlying illness or condition.

If your research injury is paid for by the University, we will collect your name, date of birth, gender, and Medicare Health Insurance Claim Number or Social Security Number to determine your Medicare status. This information will be used only in accordance with the law. If you are a Medicare beneficiary, information about the study you are in, and any payments made related to your injury, will be reported to the Centers for Medicare & Medicaid Services (CMS), in accordance with CMS requirements. This information will not be used for any other purpose.

Costs

There will be no cost to you to participate in this study. Insurance will not be billed for any procedures associated with the study.

Payments

You will be paid $35 for each visit completed in this study, and $100 for each individual skin biopsy. You will not be paid for visits that you do not complete. You will be provided prepaid credit cards at the time of each study visit, or can be reimbursed through UR Financials.

For this study we use a subject payment system called Advarra Participant Payments. The system allows three ways to provide payment. You can choose: a reloadable debit card; direct deposit; or mailed paper checks. The study team will help you create a “subject profile” in the system. In order to provide payment, you will need to enter your name and date of birth into your subject profile which is required to set up a subject account and for customer service purposes. Depending on which payment method you choose, you may also need to enter your email address and banking information. If you already have an Advarra account (because you are in another study that uses this system), your existing profile will be used to provide payment. See the ‘Information Sheet for Advarra Participant Payments” for additional information.

Payment received for participation in research is considered taxable income. If you receive payment for your participation in studies at the University of Rochester and

its affiliates of $600.00 or more in any one calendar year, the University is required to report this information to the Internal Revenue Service (IRS) in a 1099 (Miscellaneous Income) form. You will be sent a copy of this form and a copy will be sent to the IRS. Depending on the amount you are paid, you may be asked to submit a W-9 form, which includes your Social Security Number.

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Dr. De Benedetto, receives payment for her consulting activities from Study Sponsor, Incyte Corporation. Please feel free to ask Dr. De Benedetto or other study staff any questions you may have about her role as a consultant for the sponsor.

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Confidentiality of Records and Authorization to Use and Disclose Information for Research Purposes

The University of Rochester makes every effort to keep the information collected from you private. In order to do so, all study data collected will be identified by a code number and your identity will remain unknown. All information, which is collected about you as well as collected samples that leave the clinic, will have your name removed so that you cannot be recognized by it. The study doctor will be responsible for keeping a code list which would make it possible to link your assigned number to your name. This will be kept in a safe place to ensure that in case of an emergency you can be identified and contacted. The code list will be kept until the last marketing application has been received for the study drug. Sometimes, however, researchers need to share information that may identify you with people that work for the University, regulators or the study sponsor. If this does happen we will take precautions to protect the information you have provided.

If you have never received a copy of the University of Rochester Medical Center (URMC) and Affiliates Notice of Privacy Practices, please ask the investigator for one.

What information may be used and given to others?
The study doctor will get your personal and medical information. For example:

- Research records
- Records about phone calls made as part of this research
- Records about your study visits
- Past and present medical records related to the study, including records of external providers that are available via your electronic health record at URMC & Affiliates
- Results of medical tests

Who may use and give out information about you?

- The study doctor and the study staff

- URMC and Affiliates

Your information may be given to:

- The Department of Health and Human Services
- The University of Rochester
- Incyte, Corp.
- The U.S. Food and Drug Administration (FDA) may also need to inspect study records at some point during the study or even after it has been completed. In the event that this should occur, every effort will be made to keep identifying information about you private.

Why will this information be used and/or given to others?

- To do the research
- To study the results
- To see if the research was done correctly

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this research study.

May I review or copy my information?
Yes, but only after the research is over.

How long will this permission be valid?
This permission will last indefinitely.

May I cancel my permission to use and disclose information?
Yes. You may cancel your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. Upon receiving the written notice, the study team will no longer use or disclose your health information and you will not be able to stay in this study. Information that has already been gathered may need to be used and given to others for the validity of the study.

May I withdraw from the study?
Yes. If you withdraw your permission to be in the study, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?
No. There is a risk that your information will be given to others without your permission.

Future Use of Information/Samples

Your information and/or samples might be distributed or used for future research studies without additional informed consent. All identifiers will be removed before your information and/or samples are used or distributed. You will be given the option at the end of this consent form to decide if you would like your information and/or samples used for future research.

Circumstances for Dismissal

You may be withdrawn from the study if your disease becomes worse or if your doctor feels that staying in the study is harmful to your health.

Early Termination

If you at any point meet the exclusion criteria established in this protocol, the study drug will be discontinued. Exclusion criteria specifically for the skin biopsy portion of this study consists of allergy to lidocaine or epinephrine. General exclusion criteria consist of pregnancy and untreated tuberculosis or hepatitis. Standard treatment will proceed as necessary to ensure optimal health for the subject.

New Study Information

If we discover any new information that might make you change your mind about continuing in the study, we will let you know.

Sponsor Support

The University of Rochester is receiving payment from Incyte, Corp. for conducting the research study.

Commercial Profit

We will use your information and/or samples for research only. However, the results of this research might lead to the development of products (such as a commercial cell line, a medical or genetic test, a drug, or other commercial product) that could be sold by a company. You will not receive money from the sale of any such product.

Return of Research Results

In general, we will not give you any individual results from your participation in the study. If we find something of urgent medical importance to you, we will inform you, although we expect that this will be a very rare occurrence.

Contact Persons

For more information concerning this research or if you feel that your participation has resulted in any research related injury, emotional or physical discomfort, please contact**:** Dr. Christopher Richardson at 585-273-4195 or any member of the research team.

Please contact the University of Rochester Research Subjects Review Board at 265 Crittenden Blvd., CU 420628, Rochester, NY 14642, Telephone (585) 276-0005 or (877) 449-4441 for the following reasons:

- You wish to talk to someone other than the research staff about your rights as a research subject;
- To voice concerns about the research;
- To provide input concerning the research process;
- In the event the study staff could not be reached.

Voluntary Participation

Taking part in this study is voluntary. You are free not to take part or to withdraw at any time, for whatever reason. No matter what decision you make, there will be no penalty or loss of benefit to which you are entitled. In the event that you do withdraw from this study, the information you have already provided will be kept in a confidential manner.

For employee-subjects: Taking part in this research is not a part of your duties, and refusing will not affect your job. You will not be offered or receive any special job-related consideration if you take part in this research.

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Use of E-mail and Text Messaging in Research

You have the option to receive communications about this study via email and/or text messaging, by indicating your consent at the end of this form. Email communications between you and the study team may be filed in your research record.

Email and/or text messages may be used to share reminders for your appointments and reminders to document your symptoms. Email and/or text communications may be sent or received in an unencrypted (unprotected) manner. Therefore, there is a risk that the content of the communication, including your personal information, could be shared beyond you and the study team. Your consent below indicates that you understand this risk. The University of Rochester is not responsible for any interception of messages sent through email/text.

For text messages:
You are responsible for any fees charged by your carrier's service plan for text messaging.
You may decide not to receive or send text messages with research study staff at any time, in person or by sending the research number a text message that says "Stop Research Text".
Your consent, and any request to stop email or text messaging, applies to this research study only.

CONSENT TO FUTURE USE OF INFORMATION / SAMPLES

May we share your samples, health information, and genomic information with other researchers to study lupus?

Yes No

May we share your samples, genomic data, and health information with other researchers for future research projects related to other topics?

Yes No

CONSENT TO RE-CONTACT

May your study doctor, or someone from the study team, contact you in the future about using your samples or information for research that is not described in this consent form?

Yes No

May your study doctor, or someone from the study team, contact you in the future to see if you would like to participate in other research?

Yes No

___ I consent to the use of email in this study.

___ I consent to the use of text messaging in this study.

SIGNATURES/DATES

After reading and discussing the information in this consent form you should understand:

- Why this study is being done;

- What will happen during the study;
- Any possible risks and benefits to you;
- Other options you may have instead of being in the study;
- How your personal information will be protected;
- What to do if you have problems or questions about this study.

Subject Consent

I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I agree to participate in this study. I have received (or will receive) a signed copy of this form for my records and future reference.

_____
Subject Name (Printed by Subject)

_____ _____
Signature of Subject Date

Person Obtaining Consent

I have read this form to the subject and/or the subject has read this form. I will provide the subject with a signed copy of this consent form. An explanation of the research was given and questions from the subject were solicited and answered to the subject's satisfaction. In my judgment, the subject has demonstrated comprehension of the information. I have given the subject adequate opportunity to read the consent before signing.

_____
Name and Title (Print)

_____ _____
Signature of Person Obtaining Consent Date