Official Title: Eucrisa for Atopic Dermatitis:Measuring and improving Adherence to Topical Eucrisa in patients with Atopic Dermatitis
NCT03250663
IRB Approval Date: 07/30/2019

Wake Forest®
School of Medicine

Department of Dermatology

EUCRISA FOR ATOPIC DERMATITIS

Informed Consent Form to Participate in Research
Lindsay C. Strowd, M.D., FAAD, Principal Investigator

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 mild to moderate atopic dermatitis. 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 determine how well the topical crisaborole 2% ointment (Eucrisa®) works on your mild to moderate atopic dermatitis if you use it twice daily on your infected area.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Forty (40) people at this one site, Wake Forest University Health Sciences, will take part in this study, including approximately twenty (20) ages 2-17 years and twenty (20) ages 18-64 years old. In order to identify the 40 participants needed, we may need to screen as many as 60 because some people will not qualify to be included in the study.

WHAT IS INVOLVED IN THE STUDY?

You will be randomized into one of two study groups. Crisaborole 2% ointment is approved by the Food and Drug Association (FDA) for the standard treatment of mild-to-moderate atopic dermatitis. In this study, you will receive standard care topical crisaborole 2% ointment for your atopic dermatitis or you will receive standard care topical crisaborole 2% ointment for your atopic dermatitis plus a weekly internet survey. The internet survey will ask you how often you have used the medication that week, as well as a variety of questions about your experience using crisaborole 2% ointment.

If you take part in this study, you will have the following tests and procedures:

Visit 1 (Baseline)

Each participant will be screened to determine eligibility before study medication is dispensed. Events to be conducted at this visit are:

- Obtain written informed consent/assent prior to performing any study procedures and document this in the source records.
- Medical history/review of systems and medications.
- Examination of skin to note extent of atopic dermatitis involvement.
- Complete study Questionnaires
- Perform pregnancy test on females of childbearing potential.
- If eligible, dispense study medication
- Dispense medication use diary

Visit 2 (1 month), Visit 3 (3 month), and Visit 4 (6 month) follow up

- Complete Study Questionnaires
- Examination of skin to note extent of atopic dermatitis involvement.
- Study medication tubes will be weighed.
- Concomitant medications query.
- Perform pregnancy test on females of child bearing potential. (6 month visit)
- Collect medication use diary from previous months, dispense new medication use diary

Visit 5 (12 Month – End of study)

- Complete Study Questionnaires
- Examination of skin to note extent of atopic dermatitis involvement.
- Study drug tubes will be weighed and adherence data will be downloaded.
- Pregnancy testing for females of childbearing potential
- Collect used and unused medication tubes and subject diary
- End of study feedback session

HOW LONG WILL I BE IN THE STUDY?

You will be in the study for about twelve (12) 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. You may withdraw or be removed from the study in the following instances:

1. Intercurrent illness that would, in the judgment of the investigator, affect assessments of clinical status to a significant degree, require discontinuation of drug, or both.
2. Unacceptable toxicity
3. Noncompliance
4. You request to withdraw.

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 use of the topical crisaborole 2% ointment – Eucrisa for mild to moderate atopic dermatitis we are studying include: Local irritation, itching and redness. Hypersensitivity should be suspected if severe itching or swelling occurs at the application site. There is no available data on Eucrisa in pregnant women to inform drug associated risk of major birth defects with use of topical crisaborole.

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 side effects 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.

Reproductive Risks and other Issues to Participating in Research

Due to unknown risks and potential harm to the unborn fetus, sexually active women of childbearing potential must use a reliable method of birth control while participating in this study. Reliable methods of birth control are: abstinence (not having sex), oral contraceptives, intrauterine device (IUD), Depo-Provera, tubal ligation, or vasectomy of the partner (with confirmed negative sperm counts) in a monogamous relationship (same partner). An acceptable, although less reliable, method involves the careful use of condoms and spermicidal foam or gel and/or a cervical cap or sponge. We encourage you to discuss this issue further with your physicians if you have any questions.

Contraceptive Measures for Males

Your participation in this research study may damage your sperm, which could cause harm to a child that you may father while on this study. Such harm may be currently unforeseeable. If you are sexually active, you must agree to use a medically acceptable form of birth control in order to be in this study and for one month afterward. Medically acceptable contraceptives include: (1) surgical sterilization (such as a vasectomy), or (2) a condom used with a spermicide. Contraceptive measures such as Plan B (TM), sold for emergency use after unprotected sex, are not acceptable methods for routine use. You should inform your partner of the potential for harm to an unborn child. She should know that if pregnancy occurs, you will need to report it to the study doctor, and she should also promptly notify her doctor.

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 maybe: use of the topical ointment for your mild to moderate atopic dermatitis could improve your disease.

Based on experience with topical crisaborole 2% ointment (Eucrisa®) in patients with similar disorders, researchers believe it may be as good as standard therapy you could receive without being in the study but with fewer side effects, it may be of benefit to subjects with your condition. Because individuals respond differently to therapy, no one can know in advance if it will be helpful in your particular case.

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:
You could be treated with topical crisaborole 2% ointment (Eucrisa®) even if you do not take part in the study.

Most common standard of care alternative procedures include: application of moisturizers, limited use of nonsoap cleansers, and use of wet-wrap therapy with or without a topical. The apparent risks with the above listed standard alternatives are rather low.

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.

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.

WILL YOU BE PAID FOR PARTICIPATING?

You will be paid $100 if you complete all the scheduled study visits. If you withdraw for any reason from the study before completion, you will be paid $20 for each complete study visit.

To receive payment, you must provide your social security number, name and address so that we can comply with IRS (Internal Revenue Service) reporting requirements. When payments are reported to the IRS we do not let them know what the payment is for, only that you have been paid. If you do not wish to provide this information, you can still take part in this study but you will not be paid.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by Wake Forest University Health Sciences (WFUHS). Pfizer is providing money or other support to WFUHS to help conduct this study. The researchers do not, however, hold a direct financial interest in the sponsor or the product being studied. WFUHS has applied for a patent for electronic survey programs and has started a company to provide such services.

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 Dr. Strowd at [redacted] or [redacted] after hours.

What About My Health Information?

WFU School of Medicine
Institutional Review Board
IRB Number:IRB00045841
Meeting Date Approved 7/30/2019
Version Valid Until: 7/29/2020

In this research study, any new information we collect from you and/or information we get from your medical records about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes**:** medical history, prior and current medications, allergies, demographic information such as name, address, date of birth and social security number.

If this research study involves the diagnosis or treatment of a medical condition, then Protected Health Information collected from you during this study may 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.

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), 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.

1) Monitors, auditors, IRB or other regulatory agencies will be granted direct access to the participant's original medical record for verification of clinical trial procedures or data, without violating confidentiality of the participant and to the extent permitted by other applicable laws.

2) Representatives from government agencies such as the US Food and Drug Administration (FDA), the Department of Health and Human Services (DHHS),

3) And representatives of Pfizer.

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health

Information is shared with any of these groups it may no longer be protected by federal or state privacy rules.

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. You will not be able to obtain a copy of your Protected Health Information in the research records until all activities in the study are completely finished.

You can tell Dr. Strowd 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:

Lindsay C. Strowd, M.D., FAAD
[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.

If you choose to participate in this study, your medical record at Wake Forest University Baptist Medical Center will indicate that you are enrolled in a clinical trial. Information about the research and any medications or devices you are being given as a participant may also be included in your medical record. This part of the medical record will only be available to people who have authorized access to your medical record. If you are not a patient at this Medical Center, a medical record will be created for you anyway to ensure that this important information is available to doctors in case of an emergency.

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

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 your condition worsened, it is in your best medical interest, new information becomes available, you had an unexpected reaction, you failed to follow instructions, or because the entire study has been stopped.

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, Lindsay C. Strowd, M.D., FAAD at telephone number [redacted] or after hours at [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].

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

WFU School of Medicine
Institutional Review Board
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