Official Title: Epidermal Permeability Barrier Function and Stratum Corneum Hydration of Rosacea Following Application of Ivermectin

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Wake Forest®
School of Medicine

Department of Dermatology

EPIDERMAL PERMEABILITY BARRIER FUNCTION AND STRATUM CORNEUM HYDRATION OF ROSACEA FOLLOWING APPLICATION OF IVERMECTIN

Informed Consent Form to Participate in Research
Steven R. Feldman, MD, PhD Principal Investigator

SUMMARY

You are invited to participate in a research study. The purpose of this research is to determine the effect of daily ivermectin therapy on skin hydration and rosacea treatment outcomes to prevent disease relapse. You are invited to be in this study because you have a diagnosis of rosacea. Your participation in this research will involve two in-office visits over the course of three months.

Participation in this study will involve an initial screening visit and a final visit. All research studies involve some risks. The risk of harm of discomfort is not expected to be more than a daily life of routine physical or psychological exam or test. 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. This is not a treatment study. Your alternative is to not participate in this study. 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 Steven Feldman, MD, PhD. If you have questions, suggestions, or concerns regarding this study or if you want to withdraw from the study his contact information is:

Steven R. Feldman, M.D., Ph.D.
[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 a diagnosis of rosacea, are 18 years or older, do not have a known allergy to ivermectin, have a smartphone, and have a working knowledge of English. 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 the effect of routine measurement of skin hydration levels and weekly electronic interactions in the form of a survey on patient adherence to ivermectin therapy.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

30 people at one research site will take part in this study.

WHAT IS INVOLVED IN THE STUDY?

If you agree to participate in this study, you will be asked to read and sign this consent before any study-related procedures are performed.

At your first study visit you will have your initial screening visit at the Department of Dermatology at Wake Forest Baptist Health. During your first study visit demographic information will be collected and you will complete several questionnaires pertaining to quality of life, accountability, your relationship with your physician, and severity of your rosacea. The moisture level of your face will also be measured at the start of the study with a gpskin device. You will be provided with ivermectin cream for the duration of the study and instructed to apply the medication once daily to your face.

You will be randomized to one of three study groups. Randomization means that you have an equal, random chance of being placed into any of the three groups.

Group 1 – You will apply the ivermectin cream to the face once a day for duration of the study (3 months).

Group 2 -- You will apply the ivermectin cream to the face once a day for duration of the study (3 months). You will also receive a short weekly electronic survey to your email regarding your study progress which you will be asked to complete.

Group 3 -- You will apply the ivermectin cream to the face once a day for duration of the study (3 months). You will also measure your skin's hydration levels daily throughout the study using the GPSkin device that we will provide to you. You must connect this device to your smartphone to read the results. You will have this device for the duration of the study and must return it at your final visit. The study staff will instruct you on how to use this device at home. Throughout the three-month study period you will provide daily information on rosacea treatment adherence

through a medication diary that we will provide to you.

All groups: At your second and final study visit, you will complete several questionnaires related to your participation in the study and pertaining to quality of life, accountability, your relationship with your physician, and severity of your rosacea. The moisture level of your face will be measured again at the end of the study with the gpskin device. Medication weights will be measured at each of the two office visits.

HOW LONG WILL I BE IN THE STUDY?

You will be in the study for three 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?

One risk of being involved in this study is a rare sensitivity to the Ivermectin cream. This study will also involve the use of a device (GPSkin) which uses an external sensor to measure the hydration levels of your skin. As this device uses completely noninvasive technology, there is little risk associated with its use. The GPSkin device emits radio waves at a frequency of 2.4 GHz ISM band, and at an output power of maximum 10mW (10dBm); the GPSkin device is Bluetooth LE 4.1 version compliant. In patients with implanted medical devices, this means that if the implanted medical device is affected by Bluetooth LE devices such as smartphones or Bluetooth Low Energy (BLE) wireless earphones, the GPSkin device is likely to have the same effect. The risk of harm or discomfort that may happen as a result of taking part in this research study is not expected to be more than in daily life or from routine physical or psychological examinations or tests. You should discuss the risk of being in this study with the study staff. 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: improved rosacea and adherence to rosacea treatments.

WHAT OTHER CHOICES ARE THERE?

This is not a treatment study. Your alternative is to not participate in this study.

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.

Device provided by GPSkin will not be billed to patient/insurer: Neither you nor your insurance company will be billed for the investigational device. The device is your responsibility during the study. If the device is lost or stolen, you will not be provided with another device and your participation in the study will be ended. You must return the device after completion of the study.

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 $50 upon completion of the study.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by Galderma Laboratories. The sponsor is providing money or other support to Wake Forest University Health Sciences to help conduct this study.

WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any new information we collect from you about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes**:** quality of life, accountability, and severity of rosacea information. It also includes demographic information such as sex, age, ethnicity, and email addresses.

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, Galderma; 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), 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.

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 an indeterminate period of time. This authorization does not expire. 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. Feldman 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:

Steven R. Feldman, M.D., Ph.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 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, Dr. Feldman at [redacted] or after hours through the hospital operator 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] 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

WFU School of Medicine
Institutional Review Board
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