Title: Pilot Studies Testing Levels of P63 in Psoriasis Skin Lesions

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INFORMED CONSENT AND AUTHORIZATION

PILOT STUDIES TESTING LEVELS OF P63 IN PSORIASIS SKIN LESIONS

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Sponsor(s) name and address:

Department of Pharmacology & Toxicology
3640 Colonel Glenn Hwy
Dayton, Ohio 45435

Site(s) where study is to be conducted:

Wright State Physician's Building
725 University Blvd
Dayton Ohio 45435

Phone number for subjects to call for questions:

Subjects can call the Pharmacology Translational Unit at (937) 245-7500 or (937) 775-2463

Key Information Summary

The purpose of this study is to understand the role of a specific protein, tumor protein p63 in the skin disease psoriasis. There have been a few studies suggesting that p63 is increased in psoriasis skin lesions, yet, no studies have tested this. These studies are designed to find out exactly if the p63 protein is increased in psoriasis to allow more studies, in particular for a future larger grant application. You are invited to take part in this study if you have psoriasis lesions especially on your elbow area that have not been treated recently. Or, you do not have psoriasis (as a CONTROL subject). These

studies consist of small skin biopsies to allow scientists to measure p63 and other factors in your skin.

Your participation in this study is 1 visit (may last about 1 hour).

Potential risks you may experience include:

- Skin biopsies: Risk of allergic reaction to the local anesthetic lidocaine, risk of small scar at the biopsy sties, risk of bleeding from the biopsy site
- Photography: Possible loss of confidentiality

Additional risks are listed on page 5.

Benefits

You may not benefit by participating in this study. The information collected may not benefit you directly; however, the information may be helpful to others by providing us with an understanding of psoriasis as a disease process.

Alternatives

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

Introduction and Background Information

The study is being conducted under the direction of Dr. Jeffrey Travers, Principal Investigator. Dr. Craig Rohan is serving as a sub-investigator. The study visits and procedures will all occur at the Wright State Physician Health Center, Dermatology Clinic. The total number of subjects will be 40 or less. Candidates for this study include men and women who have been diagnosed with plaque psoriasis and those who do not have plaque psoriasis

Plaque psoriasis is a skin disorder characterized by thick, red rashes with scales. This disease is caused by hyperproliferative (overactive) skin and immune cells. Although psoriasis is well studied, there are certain aspects of the disease that have yet to be fully investigated. For example, certain proteins that are likely involved in the disease process have not been reliably measured in those affected by the disease.

Tumor protein 63 or p63 belongs to a group of proteins involved in cell growth. This tumor suppressor gene (a gene associated with the development of cancer) has been involved in cells growing abnormally in many tissue types. Studying the role of this

protein in psoriasis is a relatively novel endeavor, yet warranted as excess cell growth is involved in both cancer and psoriasis.

The purpose of this consent form is to give you information about this research study. It will describe the purpose, procedures, benefits, risks, and discomforts of this study. Dr. Jeffrey Travers and the study staff will discuss this study with you and explain everything in detail. Please ask them to explain any words or information that you do not clearly understand.

It is up to you to decide whether or not to take part in this study. If you choose not to participate, your decision will not affect your current or future relationship with Wright State Physicians. If you decide to participate, you are free to withdraw at any time without affecting that relationship. Please read this entire consent form and take your time to make your decision. We encourage you to talk to your doctor, your family, and/or your friends before you decide. Any questions that arise about the study will be answered by Dr. Jeffrey Travers at any point in time.

Who is conducting and funding this research study?

Wright State Physicians (WSP) Pharmacology Translational Unit will be conducting this trial under the direction of Dr. Jeffrey B. Travers, principal investigator. The study will be funded by a grant from the Department of Pharmacology & Toxicology.

Why is this research study being done?

The purpose of this study is to further understand how a psoriasis lesion happens. We are specifically investigating the role of p63, a tumor suppressor protein. An understanding of key mediators that lead to psoriasis might aid in the discovery of more effective treatments for this skin disorder.

Why am I being asked to participate in this research study?

You have been chosen to participate in this study because you have self-identified as having plaque psoriasis or you do not have plaque psoriasis

How many people will be in this study?

Up to 40 subjects (20 with psoriasis, 20 who do not have psoriasis) may be involved in this research at Wright State Physicians.

What will happen if I take part in this research study?

Your participation in this study will be 1 visit which may last about 1 hour.

Day 0: (About 1 hour)

1. Informed consent
2. Photography and assessment of disease extent:
   Psoriasis and medical history will be collected including any treatment data. A Psoriasis Area and Severity Index (PASI) score will be obtained for all participants to measure extent and severity of psoriasis. Photographs will be taken of active lesions of psoriasis subjects [and of similar areas for control subjects].
3. Skin biopsy:
   - Psoriasis Subjects: two 5 mm (1/5th inch) skin biopsies will be obtained, with one from the lesional skin and one from non-lesional skin at least 10 cm away from an active lesion.
   - Control Subjects: a single 5 mm skin biopsy will be taken a similar area.

For the skin biopsies, the skin will be prepared in the usual sterile manner and anesthetized with 1% lidocaine with 1:100000 epinephrine. The lidocaine is a numbing medication and the epinephrine is used to decrease bleeding from the skin. The punch biopsy consists of cutting a round hole 5 mm across in the top layer of skin. If needed, a suture will be placed. If sutures are placed, then we will ask you to return for suture removal in 10-14 days. The biopsies will be coded and taken to the laboratory for Dr. Madhavi Kadakia, who will be doing the measurements of factors.

Suture Removal: If sutures were placed for the skin biopsies, then you will be scheduled to have them removed 10-14 days after their placement.

How long will I be in this research study?

If you choose to take part, you will be in the study for 1 visit (about 1 hour). If sutures are placed, you may be asked to return in 10-14 days for suture removal.

Can I stop being in this research study?

If you decide to participate, you are free to withdraw your consent and discontinue participation at any time without any penalty. Your decision will not affect your ability to receive medical care for your disease and you will not lose any benefits to which you

would otherwise be entitled. If you withdraw from the study, or the study is stopped for any reason, there is minimal risk of harm to you.

The principal investigator or study staff may also withdraw you from the study without your consent for one or more of the following reasons:

- Failure to follow the instructions of the research study staff.
- You need treatment not allowed in the study.
- The study is cancelled.
- The principal investigator believes it is in your best interest.

What are the potential risks and discomforts from being in this research study?

Potential risks you may experience include:

1. Skin biopsies: Risk of allergic reaction to the local anesthetic lidocaine, risk of small scar at the biopsy sites, risk of wound infection at the biopsy sites, risk of bleeding from the biopsy site, risk of allergic reaction to suture material.

2. Photography: The risk of photography is the possible loss of confidentiality. Pictures will not be of recognizable body parts or markings. Photos will be labeled with the study number and a code that does not identify the subject. Photos will not include any identifying information.

3. PASI Measurement: There is no risk to this non-invasive measurement.

4. There is also the potential risk of loss of confidentiality, but this will be minimized as your medical information and family history will be coded. Samples will be labeled with numeric numbers --001, 002, 003 etc. and the study number (XXXX). Example XXXX-001.

5. In addition, you may experience harms that we have not included here.

Are there benefits to taking part in this research study?

You may not receive any personal benefit from being in the study. The information collected may not benefit you directly; however, the information may be helpful to others by providing us with a more complete understanding of psoriasis in the context of p63. This knowledge will help make it possible to provide the best type of treatment for patients in the future. While you may or may not personally benefit from being in this study, your participation will provide a benefit to others with this condition and to society.

What other options are there?

You have the option to not participate in this study. If you decide not to participate in this study, there is other care available to you, such as:

- Getting treatment or care without being in a study
- Taking part in another study

The study doctor will discuss these with you.

What about privacy and confidentiality?

Total privacy cannot be guaranteed. We will protect your privacy to the extent permitted by law. If the results from this study are published, your name will not be made public. Once your information leaves our institution, we cannot promise that others will keep it private.

All conversations and procedures will take place in the Wright State Physicians' building in the dermatology clinic in a private examining room. The data will be kept in the locked office of the PI. Samples and pictures from subjects will be coded by numbers as outlined above. Photos will not be of recognizable body parts or markings.

Identifiers will be removed from your identifiable private information (or/and identifiable biospecimens). After such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without your (or your legally authorized representative's) consent.

FDA Clinical Trial Registry

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 website at any time.

What if I am injured as a result of my participation in the research study?

If you feel that you have been injured as a result of participating in the research, contact the research office or Dr. Travers at (937) 245-7500 to talk to them about your illness or injury.
If you are injured by being in this research study, you will be treated appropriately with no physician cost from Dr. Travers, though a pharmacy fee could be incurred if prescriptions are required. There are no plans for Dr. Travers and Wright State

Physicians to provide other forms of compensation (such as lost wages or pain and suffering) to you for research related illnesses or injuries.

By signing this form you will not give up any legal rights.

What are the costs for participating in this research study?

There will be no costs to you for any of the procedures or testing done as part of this research study

Will I be reimbursed for any of my expenses or paid for my participation in this research?

You will be paid for participating in this study. If you don't complete the study, you will be paid for procedures you do complete. You will be paid as follows:

Skin Biopsies: $25 each (Total - 2 for psoriasis subjects/ 1 for control subjects)
Total Compensation: $50 for psoriasis subjects
$25 for control subjects

Study payment will be provided after the end of the study day in person or will be mailed to the address you provided.

Will I be told about new information that may affect my decision to participate in this research study?

During the course of the study, you will be informed of any significant new research information (either good or bad), such as changes in the risks or benefits resulting from participation in the research or new alternatives to participation, that might cause you to change your mind about continuing in the research. If new information is provided to you, you may be asked to sign a consent form that includes the new information.

Who should I contact if I have questions?

Contact the research office and Dr. Travers at (937) 245-7500 if you have any questions about this study or your part in it or if you have questions, concerns or complaints about the research.

If you have any questions about your rights as a research subject, you may call the Wright State University Institutional Review Board (IRB) at (937) 755-4462. The IRB is an independent committee composed of members of the University community, staff of

the institutions, as well as lay members of the community not connected with these institutions. The IRB has reviewed this study.

What are my rights/responsibilities as a research subject?

As a subject, your responsibilities include:

- Follow the instructions of the research study staff.
- Tell the research study staff about any side effects that you may have.
- Tell the research staff if you believe you might be pregnant.
- Ask questions as you think of them.
- Tell the research staff if you change your mind about staying in the study.

While participating in this research study, you should not take part in any other research project without approval from the research staff of each study.

Authorization to Use and Disclose Your Health Information

State and Federal laws, including the Health Insurance Portability and Accountability Act (HIPAA), require researchers to protect the privacy of your health information. This section of the consent form describes how researchers, with your authorization (permission), may use and release (disclose or share) your protected health information (PHI) for this research study.

Please read this section of the consent form carefully.

If you sign this document, you give permission to Dr. Travers and his Wright State Physicians Pharmacology Translational Unit research team to use or disclose (release) the following protected health information:

- Your medical records for past medical conditions and medications related to your skin conditions
- All information (research records and medical records) created during your participation in this research study

The research team needs this information to conduct the study. The purpose of this study is to understand the role of a specific protein, tumor protein p63 in the skin disease psoriasis.

To maintain the integrity of this research, you might not have access to any health information developed as part of this study until it is completed. At that point, you generally would have access to your health information.

Disclosure of your protected health information

If you sign this form, the researchers may share your health information during the conduct of the study with:

- Non-Wright State Physicians researchers or organizations working with Wright State Physicians researchers.
- Law enforcement or other agencies, when required by law
- WSU's Institutional Review Board (or other IRB of record), which oversees our research
- The sponsor (the organization paying for) of this research study: Department of Pharmacology & Toxicology
- Representatives of government agencies in the United States and other countries (i.e. Food and Drug Administration and the Office of Human Research Protection)
- Other authorized Wright State University/Physicians Officials who oversee research and clinical care

The people listed above will use and share your health information to review the quality, safety, and results of the research and may also do additional research.

Please understand that these persons/organizations who may receive your health information may not be required by U.S. Federal privacy laws (such as HIPAA) to protect it and may share your information with others without your permission.

This authorization does not have an expiration date.

However, you can change your mind and cancel this authorization at any time. To cancel this authorization, you must write the study investigator listed at the beginning of this consent form.

If you cancel this authorization, you will no longer be allowed to take part in the research study. If you cancel this authorization, health information you had already allowed us to obtain may still be used and disclosed by researchers in order to maintain the integrity and reliability of the research, and to report any adverse (bad) effects that may have happened to you.

Right to refuse to sign this Authorization

You have the right to refuse to sign and give your authorization. If you do not sign this form, your non-research related treatment, payment or enrollment in any health plans, or your eligibility for other medical benefits at Wright State Physicians will not be affected in any way.

However, if you do not sign this form, you will not be able to participate in this research study.

Signature of Subject

I have read (or someone has read to me) the above information. I have been given an opportunity to ask questions and my questions have been answered to my satisfaction. I agree to participate in this research and authorize the use and disclosure of my protected health information for this study. I will be given a copy of this signed and dated form.

_____
Signature

_____
Date

_____
Printed Name

_____
Signature of Person Obtaining Consent and Authorization

_____
Date

_____
Printed Name of Person Obtaining Consent and Authorization