Participant Informed Consent Form and Authorization to Use and Disclose Medical Information

Study Title: A Phase 4 Pilot Study To Study the Effects of Achthar in Ocular Inflammation

Study Doctor: Rolando Toyos, MD
Melissa Toyos, MD
Jessica Armstrong, OD
Haylie Mulliniks, OD

Study Site: Toyos Clinic
1365 S Germantown
Memphis, TN 38138

Telephone: 888-315-3937 (24 hours)

Introduction

You are being asked to participate in a medical research study. Before agreeing to participate in this research study, it is important that you read the following explanation of this research study. No guarantees or assurances can be made as to the results of the study.

The decision to participate in this study is up to you. Your participation is completely voluntary. Your decision will not affect your relationship with your regular doctor or your current or future medical care.

Please read this form carefully. Feel free to discuss the study with your family, friends, and healthcare provider before you make your decision whether to participate. Ask about anything you don't understand or would like explained better. Take time to decide whether or not you want to take part in this study and ask the study doctor or study staff as many questions about the study as you would like. You cannot take part in this research study until you sign this form.

Background and purpose

You are being asked to take part in this study because you have been diagnosed with ocular inflammation.

The purpose of this study is to study the effects of Achthar on ocular inflammation.

Achthar is adrenocorticotropic hormone that is a normally secreted by your body. It can be used as a medication and diagnostic agent. This hormone stimulates the secretion of steroid hormones inside your body that may affect inflammation in parts of your body.

Your responsibilities
To learn proper administration technique for Achthar and perform it correctly at home as directed by your doctor. To present to the clinic for follow up as directed by your doctor and to report any side effects or health changes immediately to your doctor.

Potential Risks and Discomforts
There are potential risks to you by taking part in this study including risks that are currently unknown. Pregnant women are not eligible to take part in the trial. If you are a woman who may become pregnant, you must use an effective method of birth control while participating in the study. If you become pregnant during the study, please let your study staff known immediately and cease use of the study product. You should tell your study doctor about physical or emotional changes or side effects that may occur while taking part in this study. Promptly report any health problems or changes to a member of the study staff or your study doctor.

Potential Benefits
You may benefit as a result of your participation in this study. However, there is no assurance that you will benefit from your participation in this study. Results from this study may benefit other patients in the future.

Your ocular inflammation may worsen, improve or stay the same while receiving the study product.

Alternative Treatment
This clinical study is for research purposes only. You do not have to participate in the study to receive treatment for ocular inflammation. There are other options available to you including topical, oral and IV steroids, non-steroidals, biologic agents and steroid sparing agents including but not limited to plaquenil or methotrexate .

Costs
There will be no charge to you for your participation in this study. The study product, study-related procedures and study visits will be provided to you at no charge or to your insurance company.

Voluntary Participation/Withdrawal

Your decision to participate in this clinical research study is voluntary. You may choose not to participate or you may withdraw from the study for any reason at any time without penalty. You should tell the study doctor or study team if you decide to leave the study.

The study doctor can stop the study or your participation in the study at any time without your consent if it appears to be medically harmful to you, if you fail to follow directions for participating in the study, if the study is canceled, or for administrative reasons. If you withdraw

or are withdrawn from the study, you will no longer receive access to study product but may be asked to continue in the study for safety measures.

Confidentiality

Your identifiable health information is protected by a federal law called Health Insurance Portability and Accountability Act of 1996 (HIPAA). You will be asked to review and sign a separate HIPAA authorization form.

It is possible that regulatory agencies may inspect confidential study materials and absolute confidentiality cannot be assured. However, all medical records and research materials will be held confidential. If the results of this study are published or presented at meetings, you will not be identified.

Consent

I have read the statements in this informed consent document. I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction. I voluntarily agree to participate in this study, if and until I decide otherwise. I do not give up any of my legal rights by signing this consent document. I may request a copy of this signed consent document.

Printed Name of Participant

_____ _____

Signature of Participant Date

I have carefully explained to the participant the nature and purpose of the above study. There has been an opportunity for the participant to ask questions about this research study. I have been available to answer any questions that the participant has about this study.

Printed Name of Person Conducting Consent Discussion

_____ _____

Signature of Person Conducting Consent Discussion Date

Authorization to Use and Disclose Protected Health Information

During your participation in this research study, the study doctor and study staff will collect or create health information about you and record it on study documents. The study doctor will keep this protected health information.

Under federal law, your protected health information that is created or obtained during this research study cannot be used or disclosed without your permission. This permission is called an "Authorization." You do not have to sign this Authorization, however, you may not participate in this study unless you give your permission to use and disclose your PHI by signing this authorization. By signing, you are agreeing to allow the study doctor and study staff to use your health information to conduct this study.

This Authorization will never expire unless and until you revoke (cancel or withdraw) it.

You have a right to revoke your Authorization at any time. If you revoke it, your health information will no longer be used for this study, except to the extent the parties have already taken action based upon your prior Authorization or need the information to complete analysis and reports for this research. To revoke your Authorization, you must write to the study doctor, stated that you are revoking your Authorization to Use or Disclose Protected Health Information. The study doctor's mailing address is Toyos Clinic, 1365 S Germantown, Germantown, TN 38138. If you revoke this Authorization, you will not be allowed to continue in the study.

You may receive a copy of this Authorization after you have signed it.

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Printed Name of Participant

_____ _____

Signature of Participant Date

I have carefully explained to the participant the nature and purpose of this form. I have been available to answer any questions that the participant has about this form.

_____

Printed Name of Person Obtaining the Authorization

_____ _____

Signature of Person Obtaining the Authorization Date