CONSENT FORM FOR PARTICIPATION IN A RESEARCH STUDY

Introduction

You are being asked to participate in a research study. This study is being conducted at Truman Medical Center (TMC) and Sabates Eye Centers.

The researchers in charge of this study are Dr. Sean Gratton, Dr. Ashley Abraham and Dr. Matthew Cossack. The study team is asking you to take part in this research study because you have a diagnosis of migraine headaches. Research studies only include people who choose to take part. Please read this consent form carefully and take your time making your decision. The study doctors will go over this consent form with you. Ask him/her to explain anything that you do not understand. Think about it and talk it over with your family and friends before you decide if you want to take part in this research study. This consent form explains what to expect: the risks, discomforts, and benefits, if any, if you consent to be in the study.

Background

According to the American Migraine Prevalence and Prevention study, migraine affects 29.5 million Americans. Of those affected by migraine headache, 51% reported reduced work or school productivity; and, as the third leading cause of emergency room visits, migraine headache represents a significant burden for patients and healthcare systems. Treatments for migraines do not always work well. This research study will look at a treatment that may work well and is fast-acting.

Purpose

The purpose of this study is to look at how well of the use of eye drops are in the treatment of migraine headaches. This eye drop, Timolol, is FDA approved and has been safely used for decades for the treatment of other medical conditions.

You will be one of about 50 subjects in the study at Truman Medical Center and Sabates Eye Centers.

Study Procedures and Treatments

If you chose to participate in this study, the study doctor will ask you to complete a personal health questionnaire. A thorough medical history will be obtained prior to you being enrolled in this study to make sure you are qualified to participate .You will be asked to have a complete eye and neurological (looking at your nervous system) exam. We will check your blood pressure and heart rate. If you are female and of child-bearing age, you will be given a urine pregnancy test to make sure you are not pregnant. If you are pregnant or breast feeding you cannot be in this study.

You will be randomly placed (like the flip of a coin) into one of two groups. One group will initially receive Timolol for migraine headaches. The other group will initially receive a placebo (eye drops that do not have any drug). You will be given the eye drops to use when you have a headache. You are to follow the instructions for eye drop use. You will also be given a migraine diary to track your symptoms and treatment.

You will be asked to come back to the clinic for 4 follow up visits to discuss how you are doing and to monitor your health. At each visit you will have a neurologic exam as well as measurements of intraocular pressure (the pressure inside your eye), blood pressure, and heart rate. You will be asked to bring your migraine diary and your unused eye drops. We will provide additional drops as needed.

After two months, on your third visit, we will provide you with the alternative set of drops. Patients who started with timolol will receive placebo and those that started with placebo will receive timolol. We will ask you to not use any drops for three days and then to continue with drop usage and journaling with the new set of drops. At the fifth and final visit, we will collect unused drops and your journal.

All identifying information such as your name, medical record number, date of birth, etc. will be kept confidential.

Possible Risks or Side Effects of Taking Part in this Study

Side effects from Timolol eye drops are mild and rare, but may be serious in some individuals. Adverse reactions include eye irritation, cardiovascular (heart) and pulmonary (lungs) side effects. There may be additional risks of participating in this study that we do not know about.

Possible Benefits for Taking Part in this Study

By taking part in this study you may see improvement in your migraine symptom relief. Information we collect in this study may help researchers better understand migraine headaches and may lead to better treatment of this condition. Your symptoms may or may not get better from being in this study.

Costs and Compensations for Taking Part in this Study

There are no costs to you for being in this research study. You will not receive any payment or compensation for your participation.

Alternatives to Study Participation

If you decide not to participate in this study, no changes will be made to your normal care. You will continue to receive treatment for migraine headaches whether or not you participate in this study.

Confidentiality and Access to your Records

The Bar Code at the top of this consent form will be used to link this consent form and your participation in this research study to your TMC permanent medical record. If you do not want this consent form or your participation in this study to be a part of your permanent medical record you cannot participate in this research study.

The results of this research may be published or presented for scientific purposes. You will not be named in any reports of the results. Your study or applicable medical records that have your identity in them may be shown to the Institutional Review Board (IRB) (a committee that reviews and approves research studies), the Food and Drug Administration, or other governing agencies. This is to prove which study procedures you completed and to check the data reported about you. They may also review your medical records for any treatment you received before you agreed to take part in this study. This is to confirm your medical history and that you meet the requirements to be in this study. Information about the research study will also be available online at ClinicalTrials.gov. The study team will keep all information about you confidential as provided by law, but complete confidentiality cannot be guaranteed.

If you leave the study or are removed from the study, the study data collected before you left may still be used along with other data collected as part of the study. For purposes of follow-up studies and if any unexpected events happen, subject identification will be filed at TMC under appropriate security and with access limited to medical research personnel only.

If you sign this consent form, you are allowing the study team and these other agencies to see your medical records.

In Case of Injury

Truman Medical Center (TMC) will provide medical attention to you in the event of any medical emergency while present at TMC from participation in this research, whatever the cause at the usual charge and you will have the benefit of the coverage of any existing health insurance you own.

Participation in this research study does not take the place of routine physical examinations or clinic visits to your personal physician. If you believe you have been injured as a result of participating in this study you are encouraged to contact the study investigators, Dr. Sean Gratton or Dr. Matthew Cossack, at (816) 404-3900.

The University of Missouri-Kansas City appreciates people who help it gain knowledge by being in research studies. It is not the University's policy to pay for or provide medical treatment for persons who participate in studies.

Contacts for Questions about the Study

You should contact the IRB Administrator of UMKC's Institutional Review Board at 816-235-5927 if you have any questions, concerns or complaints about your rights as a research subject. You may call the researcher Dr. Matthew Cossack at (816) 404-3900 if you have any questions about this study. You may also call him if any problems come up.

Voluntary Participation

Taking part in this research study is voluntary. If you choose to be in the study, you are free to stop participating at any time and for any reason. If you choose not to be in the study or decide to stop participating, your decision will not affect any care or benefits you are entitled to. The researchers, may stop the study or take you out of the study at any time

- If they decide that it is in your best interest to do so,
- If you experience a study-related injury,
- If you need additional or different medication/treatment,
- If you no longer meet the study criteria, or
- If you do not comply with the study plan.

They may also remove you from the study for other administrative or medical reasons. You will be told of any important findings developed during the course of this research.

You have read this Consent Form or it has been read to you. You have been told why this research is being done and what will happen if you take part in the study, including the risks and benefits. You have had the chance to ask questions, and you may ask questions at any time in the future by calling Dr. Matthew Cossack at (816) 404-3900. By signing this consent form, you volunteer and consent to take part in this research study. You will be given a copy of this consent form.

Signature (Volunteer Subject)	**Date**	**Printed Name (Volunteer Subject)**
Signature (Authorized Consenting Party)	**Date**	**Printed Name (Authorized Consenting Party)**
Relationship of Authorized Consenting Party to Subject		
Signature of Person Obtaining Consent	**Date**	**Printed Name of Person Obtaining Consent**