

RESEARCH CONSENT FORM

16-Feb-2017 -
21-Dec-2017

You are being asked to participate as a subject in the research project entitled, Comparison of blood loss intraoperative visibility between Labetalol and Esmolol: A randomized controlled trial, under the direction of Dr. Mohamad Chaaban, Assistant Professor, Department of Otolaryngology-Head and Neck Surgery.

PURPOSE OF THE STUDY

The purpose of this study is to compare the differences in visibility and blood loss between two different blood pressure medications that are routinely given during endoscopic sinus surgery. You are being asked to participate because you are scheduled to undergo a routine endoscopic sinus surgery for your chronic sinusitis.

PROCEDURES RELATED ONLY TO THE RESEARCH

You will undergo routine endoscopic sinus surgery. This research study will not alter your routine sinus surgery.

If you agree to participate, we will collect data that will be needed for the study including a survey that will be performed by the physician. Your age, and gender will also be collected, visit to the ED following discharge, need for medical attention following discharge, need for surgical re-intervention, and pain score after surgery, as well as time spent in recovery, use of anti-emetics postop, and nurses notes on as regards to pain and recovery. If you wish to withdraw consent for use of this data, you will need to contact Dr. Chaaban and inform him of your decision. Any unused data will be destroyed following your withdrawal.

PROCEDURES NOT RELATED TO THIS RESEARCH (i.e., standard of care)

Your endoscopic sinus surgery will not be altered in any way in this procedure. At the time of surgery, the diseased sinuses will be opened in a routine fashion as described in your surgical consent.

RISKS OF PARTICIPATION

The potential risks from participation in the study are possible risk from loss of confidentiality that may arise from participation in the project.

NUMBER OF SUBJECTS PARTICIPATING AND THE DURATION OF YOUR PARTICIPATION

The anticipated number of subjects involved in the study will be 40 with all subjects being selected from University of Texas Medical Branch. The length of time for your participation is only during your preoperative visit and during surgery and immediate postop when data will be recorded.

BENEFITS TO THE SUBJECT

You will not benefit from your participation in the research project.

OTHER CHOICES (ALTERNATIVE TREATMENT)

Participation in this study is voluntary. The alternative is not to participate in this study and this will not

affect the routine care that you will receive.

SAFE WITHDRAWAL FROM THE STUDY

You may withdraw at any time during the study.

REIMBURSEMENT FOR EXPENSES

There will be no reimbursement for participation in this study

COMPENSATION FOR RESEARCH RELATED INJURY

If you are physically injured because of any substance given to you or procedure properly performed on you under the plan for this study, your injury will be treated.

Compensation for an injury resulting from your participation in this research is not available from the University of Texas Medical Branch at Galveston. You, or your insurance company or health care plan, will be billed and you will be responsible for any charges.

You will be responsible for paying any costs related to illnesses and medical events not associated with being in this study. There are no plans to provide other forms of compensation. However, you are not waiving any of your legal rights by participating in this study. Questions about compensation may be directed to the study doctor.

COSTS OF PARTICIPATION

All study-related costs associated with your participation will be paid by the UTMB Otolaryngology department. You and/or your insurance company will be charged or held responsible for the costs of your routine care.

REASONS FOR THE STUDY INVESTIGATOR TO STOP YOUR PARTICIPATION

If applicable, you should list reasons that the subject's participation may be stopped without their consent. These include cancellation of your surgery for any reason.

USE AND DISCLOSURE OF YOUR HEALTH INFORMATION

Study records that identify you will be kept confidential as required by law. Federal privacy regulations provided under the Health Insurance Portability and Accountability Act (HIPAA) provides safeguards for privacy, security, and authorized access of your records. These regulations require UTMB to obtain an authorization from you for the use and disclosure of your health information. By signing this consent form, you are authorizing the use and disclosure of your health information for the purpose of completing the research study. Except when required by law, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier in study records disclosed outside of the University of Texas Medical Branch (UTMB). For records disclosed outside of UTMB, you will be assigned a unique code number. The key to the code will be kept in a locked file in Dr. Chaaban's office.

If you sign this form, you are giving us permission to collect, use and share your health information. You do not need to sign this form. If you decide not to sign this form, you cannot be in the research study. We cannot do the research if we cannot collect, use and share your health information. Whether or not you

agree to the research project or give us permission to collect, use or share your health information will not affect the care you will be given at UTMB.

Dr. Chaaban will use and disclose your study related test results both to treat you and to complete the research study. These would include your demographic information, intraoperative still images of the surgery and your hemodynamic profile including blood loss following surgery. With the exception of the images, these are routinely obtained and included in your chart. You may see or receive a copy of any research information that will be included in your medical record. For all other health information we collect on you that will not be included in your medical record, you may not be allowed to access or receive a copy of the information until the conclusion of the study.

Your records may be reviewed in order to meet federal or state regulations. Reviewers may include, for example, the Food and Drug Administration, UTMB, UTMB IRB. This authorization for the use and disclosure of your health information as described above expires upon the conclusion of the research study.

If you change your mind later and do not want us to collect or share your health information, you need to contact the researcher listed on this consent form by telephone. You need to say that you have changed your mind and do not want the researcher to collect and share your health information. You may also need to leave the research study if we cannot collect any more health information. We may still use the information we have already collected. We need to know what happens to everyone who starts a research study, not just those people who stay in it. The results of this study may be published in scientific journals without identifying you by name.

ADDITIONAL INFORMATION

1. If you have any questions, concerns or complaints before, during or after the research study, or if you need to report a research related injury or adverse reaction (bad side effect), you should immediately contact Dr. Chaaban at 409-772-2701 or, if after normal office hours, pager 409-643-0519.
2. Your participation in this study is completely voluntary and you have been told that you may refuse to participate or stop your participation in this project at any time without penalty or loss of benefits and without jeopardizing your medical care at UTMB. If you decide to stop your participation in this project and revoke your authorization for the use and disclosure of your health information, UTMB may continue to use and disclose your health information in some instances. This would include any health information that was used or disclosed prior to your decision to stop participation and needed in order to maintain the integrity of the research study. If there are significant new findings or we get any information that might change your mind about participating, we will give you the information and allow you to reconsider whether or not to continue.
3. If you have any complaints, concerns, input or questions regarding your rights as a subject participating in this research study or you would like more information, you may contact the Institutional Review Board Office, at (409) 266-9400.

The purpose of this research study, procedures to be followed, risks and benefits have been explained to you. You have been allowed to ask questions and your questions have been answered to your satisfaction. You have been told who to contact if you have additional questions. You have read this consent form and voluntarily agree to participate as a subject in this study. You are free to withdraw your consent, including your authorization for the use and disclosure of your health information, at any time. You may withdraw your consent by notifying Dr. Chaaban at 409-772-2701. You will be given a copy of the consent form you have signed.

Informed consent is required of all persons in this project. Whether or not you provide a signed informed consent for this research study will have no effect on your current or future relationship with UTMB.

Signature of Subject

Date

Using language that is understandable and appropriate, I have discussed this project and the items listed above with the subject

Date

Signature of Person Obtaining Consent