Thomas Jefferson University
Informed Consent Document for Human Subjects Research – OHR-8
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Department: Otolaryngology

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Medical Study Title: Treatment of Post-Operative Sinonasal Polyposis with Topical Furosemide

Lay Study Title: A research study to evaluate the effect of a nasal spray containing furosemide (Lasix) on nasal polyps following sinus surgery.

What Is Informed Consent?

You are being asked to take part in a medical research study. As required by federal regulations, this research study has been reviewed and approved by an Institutional Review Board (IRB), a University committee that reviews, approves and monitors research involving humans. Before a knowledgeable decision about whether to participate in a research study can be made, the possible risks and benefits related to the study should be understood. This process of learning and thinking about a study before deciding to participate is known as *informed consent* and includes:

- Receiving detailed information about this research study;
- Being asked to read, sign and date this consent form once the nature of the study is understood and a decision is made to participate. If there is anything about the study you don't understand or if there are questions, you should ask for explanations before signing this form;
- Being given a copy of the signed and dated consent form to keep.

A patient who joins a research study has a relationship with the study doctor that is different than the relationship with a treating or personal doctor. A treating doctor treats a specific health condition with the goal of improving that condition. A study doctor treats all subjects according to a research plan to obtain information about the experimental drug, device or procedure being studied and with the understanding that there may or may not be benefit from being in the study. The study doctor and study staff can provide more information about research as opposed to treatment.

The type of study you are being asked to join is known as a pilot study.

A pilot study is one that is done to collect information to determine whether a larger, scientifically rigorous study should or should not be undertaken.

Thomas Jefferson University IRB/OHR
Approval Date: 11/20/20
Expiration Date: 3/10/21
Annual review due 6 wks before expiration

What is the purpose of this study?
This study aims to evaluate if topical furosemide may reduce or prevent the recurrence of sinonasal polyposis following sinus surgery.

How many individuals will participate in the study and how long will the study last?
100 patients will participate nationally. We hope to enroll **all** patients at Jefferson. Each participant will be in the study for about _6_ **months**

What will happen during the study?
You will be randomized into either a treatment group or a placebo group to receive a 6 week course of twice a day nasal spray after undergoing surgery for nasal polyps. You will be randomly put into either group like flipping a coin. If you are put into the treatment group you will receive furosemide in a nasal spray. If you are put into the placebo group, you will receive saline in a nasal spray. Neither you nor your doctor will be aware of what group you are in. You will receive an unmarked bottle of nasal spray. You will be given a subject diary to fill out for any days you miss a dose. Post-operative visits will be scheduled at 1 week, 3 week, 2 months, 4 months and 6 months where the effect of treatment will be assessed through a physical exam and any symptoms you may be having. These results will be compared to pre-operative values and between groups to see if a difference exists.

What are the side effects and other risks or discomforts involved?
Tell the study doctor or research team as soon as possible if any of the side effects, risks or discomforts listed below occur or if you think a side effect that is not listed may be happening.

If your condition worsens, if side effects become very severe, or if it turns out that being in this study is not in your best interest, you will be taken out of the study.

If questions come up about side effects, ask the study doctor or staff at any time during or after the study.

Common, some may be serious, could happen in 20% or more of subjects

- Nasal irritation or bleeding.

Occasional, some may be serious, could happen in 3-20% of subjects

- nausea or vomiting
- diarrhea
- constipation
- stomach cramping
- feeling like you or the room is spinning (vertigo)
- dizziness
- headache
- blurred vision
- itching or rash

Rare and serious, possible in up to 3% of subjects

- Excessive loss of water and electrolytes. Symptoms can include:
  - dry mouth
  - feeling of thirst
  - weakness
  - drowsiness
  - restlessness
  - muscle pains or cramps
  - urinating less
  - fast or abnormal heartbeat
  - severe nausea or vomiting
- Hearing loss

If the study doctor decides it is necessary, at study visits or at other times, blood tests will be done to check the function of your heart, lungs, liver, kidneys, and bone marrow (where blood cells are produced). Abnormal tests will be assessed by the study doctor who will determine if further testing is necessary. The study doctor will discuss test results with you.

Furosemide should not be taken with a group of medicines called aminoglycosides. At any point in the study, if you need to begin taking an aminoglycoside you should tell the study team and you will be taken out of the study. You will be provided with a list of the names of the aminoglycosides.

What are the risks to fetuses, infants and pregnant women?

Pregnant women or women who are breast feeding will not be enrolled in this study. To be in this study you and your partner must practice adequate birth control measures. The study doctor will discuss acceptable methods of birth control with you. If you are a woman of childbearing potential, you will have a pregnancy test before making a decision about being in this study. The results of this pregnancy test will be made available to you.

If you become pregnant during the course of this study, you should notify the study doctor as soon as possible.

If you are a man participating in this study, you also should practice adequate birth control because of potential adverse effects on sperm. If your partner becomes pregnant during the course of the study, the sponsor may want to follow her through the pregnancy and receive information on the pregnancy outcome. She will be asked to sign a separate consent form or a release of medical information form.

If you are a person in a same sex relationship, it is not necessary for you to practice birth control. However, if you are female, you will still have to have pregnancy tests according to the study protocol.

Are there benefits from being in this study?
There may be no benefit from being in this research, but we hope that what we learn may be helpful to future patients or society in general. Possible benefits from being in the study may include: prevention or reduced recurrence of nasal polyps.

Are there alternatives to being in the study?
Participation in this study is entirely voluntary. There may be other alternatives that could be considered. These alternatives would include: the current standard of treatment involving perioperative medications and surgery without the study drug, topical furosemide.

The study doctor will provide information about the study and any alternative treatments available.

How will privacy and confidentiality (identity) be protected?
Federal regulations require that certain information about individuals be kept confidential. This information is called "protected health information" (PHI). PHI includes information that identifies an individual personally such as name, address and social security number, or any medical or mental health record, or test result, that may have this sort of information on it. The laws state that people may see and review their medical records at any time. However, in a research study, people may not see the study results or other data about the study until after the research is completed unless the study doctor decides otherwise.

The following individuals or entities may have access to your PHI and by law must protect it. These include investigators listed on this consent form and other personnel of Thomas Jefferson University, Jefferson University Physicians, and Thomas Jefferson University Hospitals, Inc. involved in this specific study, the University's Office of Human Research and the Institutional Review Board (IRB), and your health insurance company.

PHI collected during this study may also be shared with the following entities that, while not obligated by law to protect PHI, will protect it to the best of their ability:

- With any person or agency required by law.

The following information will be provided to the entities noted above:

Study data for analysis: Lund Kennedy score, Meltzer endoscopic score, SNOT-22 score

Demographic data: age, sex, past medical history, past surgical history, allergies, medications

If you develop an illness or injury during the course of participation in this study, other PHI about treating and following the condition may be generated and disclosed as it relates to this study.

PHI collected as part of this research may be used/disclosed until the end of the research study.

You may quit the study and revoke permission to use and share PHI at any time by contacting the principal investigator, in writing, at:

Dr. Mindy R. Rabinowitz, MD
Assistant Professor
Rhinology and Endoscopic Skull Base Surgery
Thomas Jefferson University
Department of Otolaryngology - Head & Neck Surgery
925 Chestnut Street, 6th floor
Philadelphia, PA 19107

Further collection of PHI will be stopped on those who quit the study, but PHI that has already been collected may still be used.

The results of clinical tests and procedures performed as part of this research may be included in your medical records. The information from this study may be published in scientific journals or presented at scientific meetings but no one will be personally identified in these publications and presentations.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

What happens in case of injury as a result of being in this study?
In the event of a research-related injury, necessary and available medical care (including hospitalization) will be provided. A research-related injury is a physical injury or illness that is directly caused by any procedure or treatment used in this study that is different from the treatment you would receive if not participating in a research study. If physical injury occurs due to any drug/substance or procedure properly given under the plan for this study, medical expenses for treating the injury will be billed to your insurance carrier. Costs not covered by your insurance, a government program or by another 3rd party may be paid for by the sponsor of this study. There is no plan to provide compensation for loss of wages, lost time from work, personal discomfort, or for injuries or problems related to your underlying medical condition(s).

If you have questions about the sponsor's agreement regarding payment for a research-related injury please discuss with the study doctor.

If a bill related to a research-related injury is received that seems wrong, please discuss it with the study doctor or research coordinator.

Is there payment for being in this study?
There is not payment for participating in this study.

Are there costs related to being in this study?
There are no costs related to being in this study.

Research Procedures

There are no charges to you or your insurance carrier for study visits or tests that are part of this research. The investigational agent will be provided by the sponsor free of charge.

Standard Testing Procedures

Standard of care procedures and doctor visits will be billed to your health insurance carrier. These are charges that would be billed to insurance whether in a research study or not. It is possible that insurance coverage may be denied. If that happens you may be responsible for some or all of these charges. The study doctor will explain which procedures, tests and doctor visits are considered standard of care.

If a bill is received that you think is wrong, please discuss it with the study doctor or research coordinator.

What if the research results in new findings?

Anything learned during the study, beneficial or not, that may affect your health or willingness to continue in the study, will be explained.

Can I be removed from the study or quit the study?

Your decision to participate in this research study is entirely voluntary. You have been told what being in this study will involve, including the possible risks and benefits.

Your participation in this research project may be terminated by the study doctor without your consent/assent for any reason that she feels is appropriate.

You may refuse to participate in this investigation or withdraw consent and quit this study without penalty and without affecting the ability to receive medical care at Thomas Jefferson University.

If you withdraw from this study, you may continue treatment with your Jefferson doctor, or you may seek treatment from another doctor of your choice.

Should you decide to withdraw from the study, please be sure to inform the study doctor. Additional tests or procedures may be needed to ensure your safety. The study doctor will explain why these tests or procedures are necessary.

CONTACT INFORMATION

If you are having a medical emergency, call 911 or go directly to an emergency room. You should let emergency personnel or providers know that you are participating in this study.

Telephone number for questions about your rights as a research participant	The Jefferson Institutional Review Board	215-503-8966
For questions, concerns or complaints about the research, or if you suspect a research-related injury	The Principal Investigator, Dr. Mindy Rabinowitz or any co-investigator listed at the beginning of this form	215 955-6760
If you have difficulty contacting the study staff	Call the Jefferson Office of Human Research	215-503-0203

If you want more information about the Jefferson Institutional Review Board or Jefferson's Human Research Protection Program, please visit our website at http://www.jefferson.edu/human_research/irb/index.cfm.

Subject Communications

Do you wish to communicate with the study staff by e-mail? YES _____ NO _____

If you checked yes, please print your e-mail address on the line below.

RISKS: Steps are taken to protect your confidentiality when sending information by e-mail. However, e-mail is not always secure. There is always the risk that personal information sent by email could be seen by someone other than you.

YOU SHOULD **NEVER** USE E-MAIL TO REPORT A SUSPECTED ADVERSE EVENT OR ANY OTHER MEDICAL PROBLEM. THESE SHOULD BE REPORTED BY TELEPHONE.

Signatures

Patient/Subject: By signing this form, you are agreeing that:

- You were given the opportunity to read this form.
- All of the information in this form was discussed with you by an investigator or other research personnel to your satisfaction.
- All your questions have been answered to your satisfaction.
- You were not pressured and you voluntarily agree to take part in this research.

Your Name	Your Signature	Date
Name of **Person Obtaining/ Assisting with Consent**	Signature of **Person Obtaining/ Assisting with Consent**	Date

The physician investigator's signature certifies that s/he personally provided the study participant with a description of the study, study procedures, risks, benefits and alternatives to participation.

Name of **Investigator or Co-Investigator**	Signature of **Investigator or Co-Investigator**	Date
Name of **Witness**	Signature of **Witness**	Date

(Witness required if the only language the subject speaks and understands is English, but the subject cannot read English, or if the subject is blind or cannot physically sign the consent form.)

☐ **Copy of Signed and Dated Consent Form Given to the Patient/Subject**

As Per University Counsel - Do Not Sign
This Consent Form After 3/10/21

Teach-Back Questions – These questions can be asked to help ensure that the patient understands the study.

☐ Check this box if these questions were reviewed with the patient.

We have gone over a lot of information. I would like to ask you a few questions to make sure I have done a good job explaining the study to you.

1. In your own words, please answer these questions about this study:
    a. Why are we doing this study (what are we trying to learn)?
    b. What things (including tests and procedures) will you have to do in this study?
    c. What are some of the risks of being in this study?
    d. What is the benefit of being in this study?
    e. How will being in this study be different than usual medical care?
    f. How long will you be in this study?
2. Taking part in this study is voluntary. What does that mean to you?
    a. If you don't want to be in this study, what are your other choices?
    b. What will happen if you chose not to be in this study?
3. What will we do to make sure your information remains confidential?
4. What other questions do you have about this study?