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Title of Study: Potential for cortisol suppression with the use of high volume nasal mometasone irrigations in varying dosages

Sponsor: Rush Department of Otolaryngology; AdvancedRx, Plymouth Meeting, PA

RUSH

Subject Information Sheet and Consent Form

Introduction

You are being invited to take part in this research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the information in this form carefully, as it may contain words you do not understand. You may wish to discuss it with your doctor, family, and friends. If there is anything that you do not understand or you would like more information, please ask questions, and the study doctor or study staff will try their best to answer them. Once the study has been explained and you have had all your questions answered to your satisfaction, you will be asked to sign this form if you wish to participate. Before anything is done for this study, you must sign this form. A copy of this signed form will be given to you.

You do not have to take part in this study. You are free to withdraw from this study at any time you choose without giving a reason. This will not affect any future care you will receive. No promises can be made about the outcome of this as far as your current condition, either positive or negative. People who take part in research are called "subjects" instead of "patients."

Why are you being invited to participate in this study?

You are being asked to take part in this study because you are older than 18 years and suffer from chronic rhinosinusitis (CRS), and you have had a previous endoscopic sinus surgery.

What is the purpose of this study?

The purpose of this study is to determine the safety of high-volume steroid irrigations of the sinuses, using a steroid formulation that may prove superior to more traditional steroid rinses.

Nasal steroid irrigations are one treatment that many otolaryngologists (ear, nose, and throat doctors) use to treat CRS effectively. Previous studies have demonstrated that steroid irrigation is overall safe, and in this study, an alternative form of steroid rinse with increased safety profile will be employed and compared. This study will study the impact of daily Mometasone nasal irrigations on the hormones of the body. Mometasone is commercially available as a nasal spray and lotion, but is not approved by the United States Food and Drug Administration (FDA) in a capsule product for nasal irrigation, that will be provided in this study.

How many study subjects are expected to take part in the study?

We expect to enroll 45 subjects in the study at Rush University Medical Center.

What will you be asked to do?

You will be evaluated for eligibility for the study. Baseline demographic (age, sex, race, national origin, etc.) Laboratory data including AM cortisol level and pregnancy testing for women of child bearing capacity and medical history data will be collected upon enrollment. Please inform the study doctor about all medications you are currently (or recently) taken, including prescription, over-the-counter or herbal medications. Do not start any new medications or supplements while in the study without discussing them with the study doctor

You will be assigned to one of three possible Mometasone dosage groups 1 milligrams, 2 milligrams, or 4 milligrams, based on first come first serve randomization (15 subjects in each dosage group) and instructed on how to perform twice-daily steroid irrigations (8 ounces of salt water per rinse). At follow up visits, you will be examined as you would normally as part of care for your sinus problem. A laboratory blood test (approximately 2 tablespoons) will be drawn twelve weeks after continued use of the irrigation, to ensure that no hormone imbalances have occurred. It will measure morning cortisol levels in the body, so you will need the blood test to be drawn as close to 7 a.m. as possible. The body's cortisol levels peak in the morning and decline through the day. If you require oral (by mouth) steroids for medical reasons, the blood level will be delayed by one month from oral steroid use. If your morning cortisol levels are abnormal, the test will be repeated and if again abnormal you will have to follow up with an endocrinologist. You or your health plan insurance company will need to pay for the visits to the endocrinologist.

How long will you be in the study?

The study has been planned for a one year duration. Your participation will end after your cortisol level is drawn after 12 weeks of continuous topical irrigation use or in case of oral (by mouth) steroids for medical reasons, the blood level will be delayed by one month from oral steroid use.

You may be removed from this study without your consent. Possible reasons may be that the study doctor decides that continued participation in the study will be harmful to you, you will need a treatment not allowed on the study, or the study is canceled.

What are the possible risks of the study?

Risks from nasal steroid irrigation

Nasal steroid irrigations are well-tolerated and adverse (bad) effects are rare. Most adverse effects associated with topical steroid use are extrapolated (derived) from known systemic (throughout the body) steroid adverse effects these include

1. Increased pressure in the eye which causes severe eye and head pain,
2. Reduced hormone production by the adrenal glands. Low levels of hormone (cortisol) can cause weakness, fatigue (feeling tired), and low symptomatic blood pressure.
3. Local nasal effects like nasal septum perforation, irritation and bleeding from nose (epistaxis)
4. Hypersensitivity reactions including rash, itching of skin (pruritus) difficulty breathing (wheezing) and swelling beneath the surface of the skin (angioedema). Swelling may occur on the feet, hands, eyes, and lips. In more severe cases, the swelling can spread to other parts of the body. Discontinue the study drug if such reaction occurs and seek immediate medical attention.

   Mometasone is believed to have very low systemic absorption and has a better safety profile than current options for steroid rinses, further limiting the risk of these adverse

effects. If you have any such adverse effects you should let your study doctor know or seek immediate medical attention.

Pregnancy risks

Women

You may not participate in this study if you are pregnant or breastfeeding. A pregnancy test is required and will be given before you can receive the study treatment. You are responsible for using an effective birth control method such as birth control pill, barrier method, (such as condoms or diaphragm), intrauterine device (IUD), hormone implants or surgical sterility while you are taking part in this study. If you become pregnant, you must notify the study doctor immediately.

Are there benefits to taking part in the study?

There may be no direct benefit to you. We hope that you will have a good response to the treatment, but this cannot be guaranteed.

Others may benefit from the information learned in this study.

What other options are there?

Instead of participating in this study, you may choose another form of treatment such as:

- Getting treatment or care for your CRS without being in this study;
- Taking part in another study;
- Getting no treatment.

How will you receive medical supply such as medicines etc.?

Advanced Rx will receive your information such as name, contact number, address to ship the medical supplies.

What about confidentiality of your information?

Records of participation in this research study will be maintained and kept confidential as required by law. Any health information of yours that is used in the present study will be de-identified prior to storing it for use in later analysis. This de-identified data will be stored on a secure server within Rush University Medical Center.

If you withdraw from this study, the data already collected from you may not be removed from the study records. The study doctor and/or study staff may ask you whether they can continue to collect follow-up data on you.

Your identity will not be revealed on any report, publication, or at scientific meetings.

In order to conduct the study, the study doctor, Dr. Tajudeen, will use and share de-identified personal health information about you. This includes information already in your medical record, as well as information created or collected during the study. Examples of the information that may be shared include your medical history, physical exam and laboratory test results. The study doctor will use this information about you to complete this research, however, it will not be associated with your name, photo, or any other identifying information.

Confidentiality and disclosure of your personal information is further described in the attachment to this form. The attachment is titled HIPAA Authorization to Share Personal Health Information in Research (2 pages).

The Rush Institutional Review Board (IRB) will have access to your files as they pertain to this research study. The IRB is a special committee that reviews new and ongoing human research studies to check that the rules and regulations are followed regarding the protection of the rights and welfare of human subjects.

A description of this clinical study 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 the Web site at any time. Please note information may not be available on ClinicalTrials.gov until the study is completed.

What are the costs of your participation in this study?

The cost of a baseline cortisol blood draw and pregnancy tests should be covered by your insurance provider as they are standard of care. Insurance coverage for the baseline morning cortisol blood draw and a pregnancy test will be checked by office staff prior to enrollment in the study. If not covered, you can choose to cover the cost.

You and/or your health/dental plan/ insurance company will need to pay for regular follow-up care for your CRS. You will be responsible for all costs that are not paid by your insurance company. You should check with your insurance company before you enroll in this research study.

You will be required to obtain a laboratory morning cortisol test after 12 weeks of continuous use of Mometasone irrigation that will be reimbursed as part of the study. The study drug mometasone will be provided free to participants in the study twice daily for 12 weeks.

Will you be compensated or paid?

You will not be paid for your participation in this study.

What happens if you experience a research related injury?

If you experience any injury or illness as a direct result of your participation in this research study, immediate treatment will be provided. However, the cost of that treatment will be billed to you or your insurance company. Please check with your insurance company regarding coverage. If you have any medical problems during the study, please contact the study doctor. He or she will explain your treatment options to you and/or help you find a place to get treatment.

Rush University Medical Center has no program for financial compensation or other forms of compensation for injuries which you may incur as a result of participation in this study.

What happens if you need emergency care?

If you need emergency care while you are participating in this study, it is important that you tell emergency personnel of your participation in this study and notify the study doctor as soon as possible.

Whom do you call if you have questions or problems?

Questions are encouraged. If there are any questions about this research study or if you experience a research related injury, please contact: Dr. Bobby Tajudeen at (312) 942-6100. Questions about the rights of research subjects may be addressed to the Rush Office of Research Affairs at 1-800-876-0772.

By signing below, you are consenting to participate in this research study. You have read the information given or someone has read it to you. You have had the opportunity to ask questions, which have been answered satisfactorily to you by the study staff. You do not waive any of your legal rights by signing this consent form.

SIGNATURE BY THE SUBJECT:

_____	_____	_____
Name of Subject	Signature of Subject	Date of Signature

SIGNATURE BY THE INVESTIGATOR/INDIVIDUAL OBTAINING CONSENT:
I attest that all the elements of informed consent described in this consent document have been discussed fully in non-technical terms with the subject. I further attest that all questions asked by the subject were answered to the best of my knowledge.

_____	_____
Signature of Individual Obtaining Consent	Date of Signature

☐ Check here if the Individual Obtaining Consent observed the signing of this consent document and can attest, to the best of their knowledge, the person signing the consent form is the subject and the person signing the form has done so voluntarily. By checking this box, the Individual Obtaining Consent does not need to sign on the Witness signature line (below).

SIGNATURE BY WITNESS/INTERPRETER:
(for use if this consent is being used as a written summary of the research along with a short form consent OR when the person obtaining consent is not the witness):

I observed the signing of this consent document and attest that, to the best of my knowledge, the person signing the consent form is the subject and the person signing the form has done so voluntarily.

_____	_____
Signature of Witness/Interpreter	Date of Signature

☐ Check here if a separate witness signature is not necessary.

SIGNATURE OF THE PRINCIPAL INVESTIGATOR:
I attest that I am aware of the enrollment of this subject in the study discussed in this consent document.

_____ _____
Signature of the Principal Investigator Date of Signature

☐ Check here if Principal Investigator obtained consent and a separate signature is not required.