The Effectiveness of Nasal Corticosteroids versus Placebo in Nasal Obstruction in Patients with Severe Nasal Septal Deviation

NCT02877485

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STANFORD CONSENT FORM

PURPOSE OF RESEARCH

You are invited to participate in a research study of the effect of intranasal steroids on nasal obstruction. We hope to learn whether or not intranasal steroids provide a significant benefit in patients with significant nasal septal deviation who experience nasal obstruction or congestion, as there is currently a requirement from many insurance providers that a trial of nasal steroids must be completed before perusing surgery to fix nasal septal deviation. You were selected as a possible participant in this study because you have told us that you experience nasal obstruction and you have been found to have a deviated septum.

Currently, standard of care therapy is for patients to undergo treatment with an intranasal steroid spray for six weeks prior to consideration for nasal surgery to address septal deviation for nasal congestion. In this study, participants will receive the standard of care therapy plus an additional six weeks of therapy with a placebo nasal spray.

If you decide to terminate your participation in this study, you should notify Sam P. Most at (650) 736 - 3223.

This research study is looking for 60 people with nasal obstruction and nasal septal deviation. Stanford University expects to enroll 60 research study participants.

VOLUNTARY PARTICIPATION

Your participation in this study is entirely voluntary. Your decision not to participate will not have any negative effect on you or your medical care. You can decide to participate now, but withdraw your consent later and stop being in the study without any loss of benefits or medical care to which you are entitled.

DURATION OF STUDY INVOLVEMENT

This research study is expected to take approximately 2 years: this is a 2 year study with 14 weeks to 8 months of active participation by each participant (depending on whether the participant elects to undergo nasal septal surgery). Each patient will receive 6 weeks of therapy with Nasacort (an intranasal steroid)

and 6 weeks of therapy with placebo therapy. There will be a two week washout period between these two therapies, meaning that during this time, patients will use no nasal sprays.

There will be follow up for either 1 month after the completion of the nasal sprays or at 3 and 6 months after nasal septal surgery, should patients elect to undergo surgery.

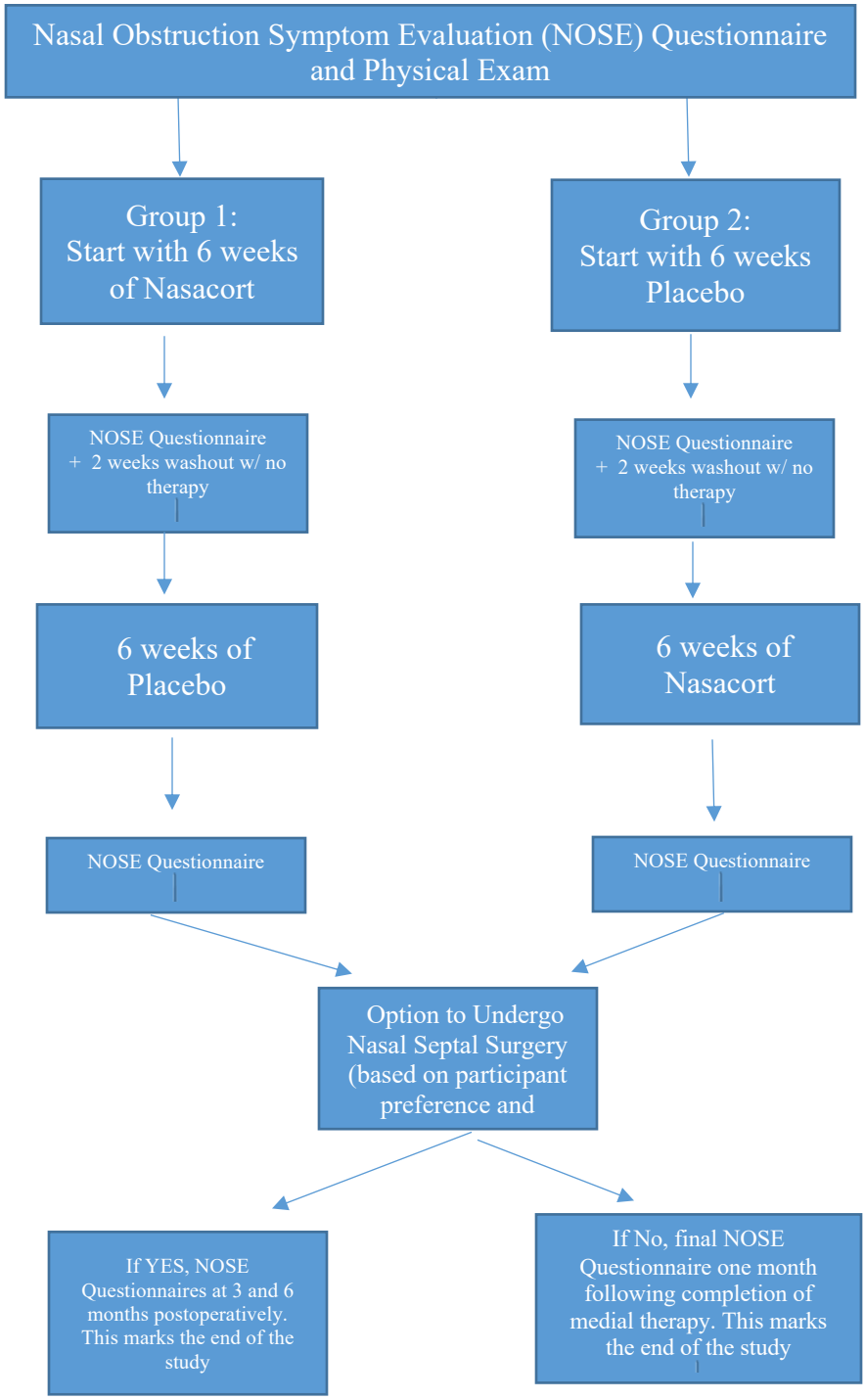
PROCEDURES

Participants will be divided into one of two study groups via random assignment (50% chance of being assigned to either group). Both groups will receive treatment with an intranasal steroid spray and a placebo treatment for 6 weeks each, though in reverse order from one another. This is called a "crossover" study.

Both sprays will be taken once a day as follows: one spray to each nostril daily. Standard of care therapy (ie what we would recommend you do for nasal obstruction even if you were not in this study) is six weeks of therapy with the intranasal steroid. As such, this study will only add on treatment with a placebo nasal spray for six weeks.

Below if a flowchart that diagrams the basic study design.

STUDY DESIGN FLOWCHART:



PARTICIPANT RESPONSIBILITIES

As a participant, your responsibilities include:

- Follow the instructions of the Protocol Director and study staff.
- Take the study drug as instructed
- Keep your study appointments. If it is necessary to miss an appointment, please contact the Protocol Director or research study staff to reschedule as soon as you know you will miss the appointment.
- Tell the Protocol Director or research study staff about any side effects, doctor visits, or hospitalizations that you may have.
- Tell the Protocol Director or research staff if you believe you might be pregnant or gotten your partner pregnant.
- Keep the study drug in a safe place, away from children and for your use only.
- Complete your questionnaires as instructed.
- Ask questions as you think of them.
- Tell the Protocol Director or research staff if you change your mind about staying in the study.
- Tell the Protocol Director or research staff if you might be pregnant or have gotten your partner pregnant during the course of this study.

WITHDRAWAL FROM STUDY

If you first agree to participate and then you change your mind, you are free to withdraw your consent and discontinue your participation at any time. Your decision will not affect your ability to receive medical care for your disease and you will not lose any benefits to which you would otherwise be entitled.

If you decide to withdraw your consent to participate in this study, you should notify Sam P. Most at (650) 736 - 3223.

If you withdraw from the study, or the study medication is stopped for any reason, you must return all study-related supplies, including any unused study drug. There are no anticipated consequences of discontinuing the study drug early. If you withdraw from the study, you will be contacted by the protocol coordinator and asked a short series of questions and then you will be removed from the list of active study participants.

The Protocol Director may also withdraw you from the study and the study medication may be stopped without your consent for one or more of the following reasons

- Failure to follow the instructions of the Protocol Director and study staff.
- The Protocol Director decides that continuing your participation could be harmful to you.
- Pregnancy
- You need treatment not allowed in the study.
- The study is cancelled.
- Other administrative reasons.
- Unanticipated circumstances.

POSSIBLE RISKS, DISCOMFORTS, AND INCONVENIENCES

There are risks, discomforts, and inconveniences associated with any research study. These deserve careful thought. You should talk with the Protocol Director if you have any questions.

Possible side effects of intranasal steroid sprays include nasal irritation, headache, cough, and unpleasant taste during administration. Rare, but more serious side effects include nasal septal perforation (development of a hole in your nasal septum) and oral candidiasis (or thrush) which is a fungal infection that requires topical treatment.

Given that all study participants will receive a placebo for 6 weeks, there is a risk that your nasal obstruction will be worse during this period than during that 6 weeks you are treated with the intranasal steroid. Similarly, during the 2 week washout period, there is a risk that your nasal obstruction will worsen as compared to when you were on the nasal steroid (if you receive the nasal steroid first).

Treatment with Nasocort and/or placebo may involve risks to the subject, which are currently unforeseeable.

Should you decide to pursue surgery for your septal deviation, there are associated risks with surgery. These will be discussed in detail at a preoperative appointment (regardless of if you enroll in this study or not). With any surgery, there is a small but non-zero risk of adverse effects to anesthesia. There is also a

risk of bleeding, infection, damage to surrounding structures (eyes, mouth, face). Additionally, there is a risk that surgery will incompletely fix your symptoms of nasal congestion.

There may be a discomfort of travel time associated with this study; however, administration of study therapies and survey materials will occur during otherwise scheduled clinic appointments and therefore this discomfort should be minimal.

POTENTIAL BENEFITS

There is a potential benefit of improved nasal congestion following treatment with Nasocort.

We cannot and do not guarantee or promise that you will receive any benefits from this study.

ALTERNATIVES

Alternatives to treatment for nasal obstruction include nasal surgery. However, as previously stated, many insurance companies require a trial of intranasal steroids prior to authorizing surgery to correct septal deviation and therefore first undergoing a trial of intranasal steroid spray is standard.

No standard treatment will be withheld as a result of being enrolled in this study. You will still have the option to undergo nasal surgery following completion of this study, if you are otherwise medically deemed appropriate for surgery.

PARTICIPANT'S RIGHTS

You should not feel obligated to agree to participate. Your questions should be answered clearly and to your satisfaction. If you decide not to participate, tell the Protocol Director.

You will be told of any important new information that is learned during the course of this research study, which might affect your condition or your willingness to continue participation in this study.

You have the right to refuse to answer particular questions that you are asked during this study.

ClinicalTrials.gov

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.

CONFIDENTIALITY

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed except as authorized by you or as required by law**.** However, there is always some risk that even de-identified information might be re-identified.

Patient information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

Authorization To Use Your Health Information For Research Purposes

Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

What is the purpose of this research study and how will my health information be utilized in the study?

The purpose of this study is to determine if there is a benefit to using intranasal steroids in the treatment of nasal obstruction/congestion in patients with a deviated nasal septum. Your health information, including the severity of your nasal septal deviation and nasal obstruction will be used to assess if there is an effect of intranasal steroids on your symptoms.

Do I have to sign this authorization form?
You do not have to sign this authorization form. But if you do not, you will not be able to participate in this research study.

Signing the form is not a condition for receiving any medical care outside the study.

If I sign, can I revoke it or withdraw from the research later?
If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any revocation, your health information will no

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longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (e.g., necessary to maintain integrity of research). If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you must write to: Dr. Sam P. Most, 801 Welch Road, Palo Alto, CA 94305.

What Personal Information Will Be Obtained, Used or Disclosed?

Your health information related to this study, may be used or disclosed in connection with this research study, including, but not limited to: First as last name, gender, date of birth, medical record number, telephone number, and electronic mail address as well as NOSE scores, physical exam findings obtained during the course of the study, and response to medical therapy and surgery.

Who May Use or Disclose the Information?

The following parties are authorized to use and/or disclose your health information in connection with this research study:

- The Protocol Director, Dr. Sam P. Most
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary
- Research Staff

Who May Receive or Use the Information?

The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

- The Office for Human Research Protections in the U.S. Department of Health and Human Services
- Food and Drug Administration

Your information may be re-disclosed by the recipients described above, if they are not required by law to protect the privacy of the information.

When will my authorization expire?
Your authorization for the use and/or disclosure of your health information will end on February 28, 2030 or when the research project ends, whichever is earlier.

Will access to my medical record be limited during the study?
To maintain the integrity of this research study, you may not have access to any health information developed as part of this study until it is completed. At that point, you would have access to such health information if it was used to make a medical or billing decision about you (e.g., if included in your official medical record).

_____ _____
Signature of Adult Participant Date

_____
Printed Name of Adult Participant

FINANCIAL CONSIDERATIONS

Payment
You will not be paid to participate in this research study.

Costs
There is no cost to you for participating in this study, other than basic expenses like transportation and the personal time it will take to come to all of the study visits.

Sponsor
The Stanford Department of Otolaryngology is providing financial support and/or material for this study.

COMPENSATION for Research-Related Injury

All forms of medical diagnosis and treatment – whether routine or experimental – involve some risk of injury. In spite of all precautions, you might develop medical complications from participating in this study. If such complications arise, the Protocol Director and the research study staff will assist you in obtaining appropriate medical treatment. In the event that you have an injury or illness that is directly caused by your participation in this study, reimbursement for all related costs of care first will be sought from your insurer, managed care plan, or other benefits program. **You will be responsible for any associated co-payments or deductibles as required by your insurance.**

If costs of care related to such an injury are not covered by your insurer, managed care plan or other benefits program, you may be responsible for these costs. If you are unable to pay for such costs, the Protocol Director will assist you in applying for supplemental benefits and explain how to apply for patient financial assistance from the hospital.

You do not waive any liability rights for personal injury by signing this form.

CONTACT INFORMATION

Questions, Concerns, or Complaints: If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the Protocol Director, Dr. Sam P. Most. You may contact her now or later at (650) 736 - 3223

Injury Notification: If you feel you have been hurt by being a part of this study, please contact the Protocol Director, Dr. Sam P. Most. You may contact her now or later at (650) 736 - 3223

Independent Contact: If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone independent of the research team at (650)-723-5244 or toll free at 1-866-680-2906. You can also write to the Stanford IRB, Stanford University, 1705 El Camino Real, Palo Alto, CA 94306.

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

As a research participant you have the following rights. These rights include but are not limited to the participant's right to:

- be informed of the nature and purpose of the experiment;
- be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
- be given a description of any attendant discomforts and risks reasonably to be expected;
- be given an explanation of any benefits to the subject reasonably to be expected, if applicable;
- be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the subject, their relative risks and benefits;
- be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise;
- be given an opportunity to ask questions concerning the experiment or the procedures involved;
- be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice;
- be given a copy of the signed and dated consent form; and
- be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

May we contact you about future studies that may be of interest to you?
____ Yes ____ No

Signing your name means you agree to be in this study and that you will receive a copy of this signed and dated consent form.

_____ _____
Signature of Adult Participant Date

_____
Printed Name of Adult Participant