IRB Approved Template
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FOR SITES BEFORE USE
AS MODIFIED
Jun 21, 2022

RESEARCH SUBJECT CONSENT FORM

Title:	A Prospective, Multicenter Study of the AERin Medical Vivaer® ARC Stylus for Nasal AirWAY Obstruction (AERWAY)
Protocol No.:	TP900 WCG IRB Protocol #20192967
Sponsor:	Aerin Medical, Inc.
Investigator:	Name Address City, State Zip Country
Study-Related Phone Number(s):	Phone Number Phone Number

RESEARCH CONSENT SUMMARY

You are being asked for your consent to take part in a research study. This document provides a concise summary of this research. It describes the key information that we believe most people need to decide whether to take part in this research. Later sections of this document will provide all relevant details.

What should I know about this research?

- Someone will explain this research to you.
- Taking part in this research is voluntary. Whether you take part is up to you.
- If you do not take part, it will not be held against you.
  You can take part now and later drop out, and it will not be held against you. There will be no penalty or loss of benefits to which you are otherwise entitled.
- You can choose not to take part. There will be no penalty or loss of benefits to which you are otherwise entitled.
- If you do not understand, ask questions.
- Ask all the questions you want before you decide.

How long will I be in this research?

We expect that your taking part in this research will last up to 36 months.

Why is this research being done?

The purpose of this research is to evaluate patient symptoms related to obstruction (blocked or partial blockage) of your nasal airway before and after a non-investigational treatment with a

medical device called the Vivaer ARC Stylus that is approved for use by doctors that perform Ear, Nose and Throat (ENT) procedures. Your doctor (who is the study doctor) feels you have a condition called nasal airway obstruction, which means the opening of the nasal cavity is partially closed which causes obstruction (or blockage) symptoms to occur. These symptoms may include difficulty breathing through your nose, increase in mouth breathing, difficulty eating with your mouth closed and other symptoms including congestion, stuffiness, headache, fatigue, sleep disturbance, daytime sleepiness and/or snoring.

You may have already tried medications and over-the-counter remedies such as breathing strips. This study will look at the results of the Vivaer treatment that is done by inserting a medical device into the opening of your nose (nostril). The medical device is used to heat tissues inside the nose. When the tissues heal, they are expected to stiffen and contract, which may help open the narrowed portion of the inside of the nose and relieve symptoms of blockage. The treatment will occur at the study doctor's office. The Vivaer treatment is non-experimental (non-investigational) and will be thoroughly described in the next section.

What happens to me if I agree to take part in this research?

This study will involve up to 125 subjects at up to 15 doctor offices in the United States. Your involvement in the study will take place up to 36 months including collection of information from screening, enrollment, treatment and follow-up which will include 1 visit to your study doctor's office after treatment. The remaining evaluations will be questionnaires answered by you either electronically on the internet, by mail or by a phone call from the study coordinator.

If you decide to take part in this research study, the general procedures include the following:

Screening Visit – Before Treatment

At the screening visit you can take your time to ask questions and understand the study before deciding whether you want to participate. By coming to the screening visit, you are not obligated to participate in the study. This is a good time to ask questions and consider the study commitment. You will not be considered part of the study until after you sign this informed consent form.

If you agree to be in the study and sign the study informed consent form, standard evaluations will be performed to understand your general state of health and to determine whether you qualify for this study. The following screening evaluations will be done:

- Demographics (e.g. age, gender, ethnicity)
- Review of medical history, including questions about your current medications and medical conditions.
- General health questions will be asked to understand health status and if you have other health concerns to consider before the Vivaer treatment.
- A nasal exam will be performed by the study doctor to understand what is contributing to your nasal obstruction.

- The inside of your nose will be examined by the study doctor with a small camera scope, about the size of a skinny straw. This part is routine and is not experimental.
- Photos and/or video of the inside of your nose will be taken for study documentation purposes.

A standard questionnaire called Nasal Obstruction Symptom Evaluation (NOSE) Scale will be completed by you that asks about your symptoms you experience with nasal obstruction to better understand the impact on your quality of life.

All study subjects who are willing to enroll and qualify for the study will be scheduled to receive the Vivaer treatment. There are no comparison groups in this study. In other words, the Vivaer treatment will not be compared to another type of treatment in this study.

During Treatment
Immediately before the treatment the study doctor will ask a few questions about the general status of your nasal area to document prior to treatment.

The Vivaer treatment will take about 30 to 45 minutes in the study doctor's office. Both of your nostrils will be treated, even though one may bother you more than the other. The study doctor will prepare the nasal valve (which is at the narrowest part of the opening of your nose) for treatment by numbing the area. This part of the treatment is not experimental and is common when treating patients for certain conditions in the nose, so your doctor will use his/her preferred method for doing this. A typical way to do this is by either placing a small cotton tip (like a long Q-tip) of numbing medication onto the surface of the inside of your nose or applying a numbing spray. This will prepare you for the next step, which is an injection of more numbing medication in the area of treatment to keep you comfortable during the Vivaer treatment. This part is also not experimental.

The study doctor will then place a probe that looks like a small straw at the opening just inside your nose. At this time the Vivaer treatment will begin, which is not experimental. The study doctor will look at the inside of your nose to identify the area to be treated. The doctor will then heat the tissues in the nose. You will hear some tones that indicate the study device is heating the tissue. Your doctor will ask that you remain still during this time. This part of the treatment should take no more than a few minutes or so for each nostril.

Care of Treated Area Immediately After Study Treatment
After the Vivaer treatment is complete, the study doctor may apply light pressure to the treated area and/or place gauze or petroleum jelly (like Vaseline) inside your nose with a cotton tip (like a Q-tip) to moisten the area treated. This part is standard and not experimental. Using a small camera scope, the study doctor will take photos and/or video of the treated areas for study documentation purposes.

The study doctor or study coordinator will then remind you of care for your nose after the treatment. The care may include the following as well as other instructions from your doctor:

- Do not blow your nose for 1 to 3 days, gently wipe with a tissue if needed.
- Try not to bump or irritate the treated area when you dress or during your normal daily activities.
- Do not immediately use nasal sprays or nasal medications. Please contact the study doctor if you have questions regarding which medications can be used.

Follow-Up After Vivaer Treatment

The study doctor will see you 3 months after your treatment to understand how you are doing. In addition, follow-up evaluations at 6, 12, 24 and 36 months after the treatment procedure will be conducted remotely either electronically on the internet, by mail or by a phone call from the study coordinator. The study doctor will do the following evaluations at this visit.

In-office evaluation (3 months):

- Perform a general evaluation of the nose cavity using a small camera scope to look at the nose tissue to understand the healing process after treatment.
- Take photos or video of the treated areas using a small camera scope for documentation, publication or presentation purposes.
- Ask you questions about any side effects or concerns you are experiencing related to your nose after treatment,
- Review current medications that you take for your health and/or for nasal symptoms.
- You will also be asked to complete 3 questionnaires: Nasal Obstruction Symptom Evaluation (NOSE) Scale, Quality of Life (QOL) and Pain Visual Analog Scale (VAS). The questionnaires will ask about your symptoms that you experience with nasal obstruction, any pain associated with the treated area as well as your satisfaction with your treatment in addition to other daily tasks related to nasal obstruction.

Remote evaluations by phone, mail or electronically on the internet (6 months, 12 months, 24 months and 36 months):

- You will be asked to complete 2 questionnaires: Nasal Obstruction Symptom Evaluation (NOSE) Scale and Quality of Life (QOL). The questionnaires will ask about your symptoms that you experience with nasal obstruction, your satisfaction with your treatment in addition to other daily tasks related to nasal obstruction, and any changes to your medications or changes in health status. These questions will be administered by phone, mail or internet, whichever is convenient for you and may take about 10 minutes to answer. The study coordinator is responsible for administering the follow-ups. It is not required to return to the doctor's office where you had the Vivaer treatment to complete these questionnaires at these time points. Unless otherwise told by your doctor, no office visit is required for 6, 12, 24 and 36 month visits.

Research subjects meeting the study requirements as planned will be exited from the study upon completion of the 36-month follow-up evaluation. If you reach the 36-month follow-up evaluation and are experiencing a new or ongoing adverse event, the study doctor will discuss the possibility for continued follow-up.

Could being in this research hurt me?

Risks from the procedure include pain, bleeding, swelling and infection. Nasal endoscopy may rarely cause nose bleeds or fainting.

There is a minimal risk of loss of confidentiality. However, we will make every effort to protect your identity.

The risks to an embryo, fetus or infant related to the surgical procedure and associated medical treatment and exams are unknown. Please consult your doctor if you plan or suspect to be pregnant.

If you send or receive a PDF copy of this signed and dated consent form by email, there may be risks of loss of privacy and confidentiality if the PDF copy of this consent form is viewed and/or stored on a personal electronic device (PED), especially if that PED is shared with other users or is lost, hacked, or subject to a search warrant or subpoena. Also, the PDF copy of the consent may not be able to be permanently removed from a PED.

Will being in this research benefit me?

The most important benefits that you may expect from taking part in this research include the data collected which may help inform other people with nasal obstruction who are considering having the Vivaer ARC Stylus treatment. It is not expected that you will personally benefit from this research.

What other choices do I have besides taking part in this research?

If you decide not to enter this study, there are other choices available. These include continuing medication by trying a different medication or device, or other therapies. Ask the study doctor to discuss these alternatives with you. You do not need to be in this study to receive treatment for your condition, including treatment with the Vivaer device.

What else should I know about this research?

Given the significant Quality of Life impact of nasal obstruction, it is important to measure not only the physical symptoms (congestion, obstruction and ability to breathe) but also the impact of those symptoms on the patient's ability to sleep and the related consequences on rest, productivity, concentration and ability to participate in the normal daily activities of work and life.

This study is intended to collect data on how long quality of life impact benefits persist.

You are planning on having treatment for nasal obstruction using the Vivaer ARC Stylus which is not experimental. Before you decide whether to be in this study, you should think about how the study will affect your time away from your daily schedule. Review the 'What Happens to Me if I Take Part in This Research' section starting on page 2 of what you will be asked to do. If you agree to take part in this study, you will first sign this Informed Consent Form before any study procedures are done.

What happens to the information collected for this research?

Your private information and your medical record will be shared with individuals and organizations that conduct or watch over this research, including:

- The research sponsor, Aerin Medical
- People who work with the research sponsor
- Government agencies, such as the Food and Drug Administration (FDA)
- The Institutional Review Board (IRB) that reviewed this research
- Department of Health and Human Services (DHHS) agencies
- Governmental agencies of other countries

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

We protect your information from disclosure to others to the extent required by law. We cannot promise complete secrecy.

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.

Who can answer my questions about this research?

If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number listed above on the first page.

This research is being overseen by an Institutional Review Board ("IRB"). An IRB is a group of people who perform independent review of research studies. You may talk to them at 855-818-2289, researchquestions@wcgirb.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

What if I am injured because of taking part in this research?

If you are injured or become ill as a result of participation in this study, contact the study doctor immediately. If you think you are having a medical emergency, call 911. No compensation is routinely available from the study doctor or Aerin Medical. Your medical expenses will be billed to you or that of your third-party payer, as it would be if you were not participating is the study.

By signing this consent form, you will not be waiving any legal rights which you otherwise would have as a subject in the research study.

Can I be removed from this research without my approval?

The person in charge of this research can remove you from this research without your approval. Possible reasons for removal include:

- if you need further treatment outside of the study.
- if you do not consent to continue in the study after being told of changes in the research that may affect you.
- if you become pregnant during the study.
- if the study is canceled by the FDA, the IRB, or the sponsor.

We will tell you about any new information that may affect your health, welfare, or choice to stay in this research.

What happens if I agree to be in this research, but I change my mind later?

If you 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 condition and you will not lose any benefits to which you would otherwise be entitled.

You will need to contact the study doctor or study coordinator at the contact information above so that the study doctor can answer any of your questions and discuss the process of withdrawing your consent. If you withdraw your permission, you will not be able to stay in this study. You will no longer receive notifications to complete the follow up questionnaires.

When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and may be shared with individuals and organizations that conduct or watch over this research. If you leave the study before the planned final visit, you may be asked by the study doctor to have some tests or procedures done so that you leave the study safely.

Will I be paid for taking part in this research?

For taking part in this research, you may be paid up to a total of $525.

Your compensation will be in the form of a debit card given which will be sent to you. You will get the following for enrolling in the study and at each time point at which you complete both questionnaires.

- Beginning of the study: $75
- 3 month follow-up: $75
- 6 month follow-up: $75
- 12 month follow-up: $100
- 24 month follow-up: $100
- 36 month follow-up: $100

You will be paid when the study questionnaires are completed for each time point. If you do not finish the study, you will only be paid for the visits and/or questionnaires you completed.

Will this research cost me anything?

Taking part in this research will not cost you anything.

Statement of Consent:

Your signature below means that you have read the above information about this study and have had a chance to ask questions to help you understand what you will do and that you agree to participate in this study. Your signature also means that you have been told that you can change your mind later if you want. You will be given a signed and dated copy of this agreement. By signing this consent form, you are not giving up any of your legal rights.

_____ ____/____/____

Signature of Research Subject Date

_____

Printed Name of Research Subject

STATEMENT OF PERSON EXPLAINING CONSENT

I have carefully explained to the subject the nature and purpose of the above study. There has been an opportunity for the subject to ask questions about this research study. I have been available to answer any questions that the subject has about this study.

_____ ____/____/____

Signature of Person Explaining Consent Date

_____

Printed Name of Person Explaining Consent

PHOTOGRAPH CONSENT

By signing this consent form, I also voluntarily consent to the taking, use, copyright, and publication of videos or photographs of the inside of my nose by the study doctor, sponsoring company, its affiliates, successors, and assignees. These images may be used as information and/or for advertising and promotional purposes. The sponsoring company will decide how the images will be used or whether they are used at all, but my name and face and/or any personal identifiers other than the inside of my nose will not be revealed.

_____ ____/____/____

Signature of Research Subject Date

_____

Printed Name of Research Subject

HIPAA Authorization Agreement
Permission to Review, Use and Release Information about You

Federal regulations give you certain rights related to your health information. These include the right to know who will be able to get the information and why they may be able to get it. If you decide to be in this study, the study doctor and research team will use and share health data about you to conduct the study. Health data may include:

- Past and present medical records
- Research records
- Records about phone calls made as part of this research
- Records about your study visits
- Information obtained during this research about
    - Medical history
    - Physical exams
    - Laboratory, x-ray, and other test results
    - Questionnaires

For this study, the research team may share health data about you with authorized users. Authorized users may include

- Representatives of Aerin Medical (Sponsor of the study).
- Representatives of the IRB (a Research Ethics Review Board that reviews this study).
- The Food and Drug Administration (FDA) and other US governmental agencies.
- Government agencies to whom certain diseases (like HIV, hepatitis, and STDs) must be reported.
- Governmental agencies of other countries.
- Other authorized users.

Once your health data has been shared with authorized users, it may no longer be protected by federal privacy law and could be re-disclosed.

Your permission to use and share health data about you will not end unless required by state law. If state law applies, your permission to use and share health data about you will end on December 31, 2067.

You may take back your permission to use and share health data about you at any time by writing to the study doctor at the address listed on the first page of this form. If you do this, you will not be able to stay in this study. No new health data that identifies you will be gathered after your written request is received. However, health data about you that has already been gathered may still be used and given to others as described in this form.

Your right to access your health data in the study records will be suspended during the study to keep from changing the study results. When the study is over, you can access your study health data.

You have the right to review and copy your health information.

If you decide not to sign this form, you will not be able to take part in the study.

STATEMENT OF AUTHORIZATION

I have read this form and its contents were explained. My questions have been answered. I voluntarily agree to allow study manager to collect, use and share my health data as specified in this form. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing this form.

_____ ___/___/___

Signature of Research Subject Date

_____

Printed Name of Research Subject

STATEMENT OF PERSON EXPLAINING AUTHORIZATION

I have carefully explained to the subject the nature and purpose of this form. I have been available to answer any questions that the subject has about this form.

_____ ___/___/___

Signature of Person Explaining Authorization Date

_____

Printed Name of Person Explaining Authorization