SinuSonic Study
NCT03906968
3/12/2019

Medical University of South Carolina
CONSENT TO BE A RESEARCH SUBJECT

TITLE OF RESEARCH: SinuSonic Study

Summary
You are being asked to participate in a research study at the Medical University of South Carolina. It is important that you understand that this is completely voluntary and it is your choice whether or not you participate.

This form describes the purpose, procedures, benefits, risks, discomforts and precautions of the study. It also describes the alternative procedures that may be available to you and your right to withdraw from the study at any time, for any reason. A member of the study staff will be present to discuss all information with you and be available for any questions you might have. When you think you understand the study, you will then be asked if you agree to take part. If you agree, you will be asked to sign this form. Once you sign it, we will give you a signed and dated copy to keep.

You may show this form to family, other doctors, and friends before you sign it. You may want to discuss it with them to help you decide if you want to be part of the study. If you do not know another doctor, but want a second opinion about this study, please ask. The study doctor will give you the name of another doctor that you can talk to.

You are being asked to participate in this study because you have been diagnosed with moderate to severe nasal congestion.

If you are interested in learning more about this study, please continue to read below.

A. PURPOSE OF THE RESEARCH

Current congestion medications are not always fully effective in the treatment of nasal congestion. The purpose of this study is to determine the efficacy and safety of SinuSonic on people with moderate to severe nasal congestion. The SinuSonic is a handheld device that utilizes sound and pressure combined with normal breathing to relieve nasal congestion. Healthy Humming, LLC is paying for this study to be done at MUSC. The investigator in charge of this study at the Medical University of South Carolina is Dr. Zachary M. Soler. The study is being done only at MUSC. Approximately 40 people will take part in this research study. MUSC, the study team, and the Principal Investigator will be paid to conduct the study. Dr. Soler is currently serving as a consultant for Healthy Humming, LLC. Dr. Soler has fully disclosed any Conflict of Interest to MUSC.

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

B. PROCEDURES

Before any study activities occur, the informed consent form must be signed.

If you agree to be in this study, the following will happen:

Visit 1 (Baseline Assessment/Initial Treatment):
If you decide that you want to be in the study, you will have the following procedures performed to find out if you qualify to be in this study:

- The study staff will review your medical history with you, including a review of your current medications. It is important that you inform your doctor or staff of all prescription and nonprescription medications, dietary supplements and vitamins that you are presently taking or have taken in the past 1 month.
- The study staff will go over any potential risks that are associated with the study.
- Your vital signs (blood pressure and heart rate) will be measured and weight collected.
- A nasal rhinosocopy will be performed by the Otolaryngologist. A nasal rhinoscopy is a test done to view the inside of the nose and sinuses. Your study doctor will observe and record any inflammation (irritation of the lining of the sinuses in your nose) and examine any nasal polyps, if they are present. Nasal polyps are painless, benign growths on the lining of the nose or sinuses.
- Urine will be used for a pregnancy test and, if positive, you will not be allowed to participate in this study.
- The baseline assessment will last for approximately 15 minutes. If you are deemed ineligible following the baseline assessment, you will not be allowed to complete the treatment component of the visit.
- You will receive instruction on how to use the SinuSonic device properly from the study team.
- Initial use of the SinuSonic device will last for 3 minutes.
- You will be given a post-treatment assessment. The post-treatment assessment will be performed 5 minutes after the completion of the baseline assessment.
- You will be asked to gauge your nasal symptoms using a Visual Analog Scale (VAS). A VAS is an instrument used to quantify a patient's symptoms severity. This process will take 5 minutes.

- You will gauge the level of nasal obstruction, any improvements to breathing, ability to smell, pain levels, and any other discomfort in addition to a Peak Nasal Inspiratory Flow (PNIF) Meter test. A PNIF test is a test designed to measure nasal inspiratory flow for assessing nasal airway obstruction. The PNIF test will take 5 minutes.
- You will be asked to perform a twice daily treatment using the SinuSonic at home and be given detailed instructions on how to use the SinuSonic for an additional two weeks.
- The baseline and initial assessment will last no more than one hour.

Visit 2 (Second assessment)

- You will be asked to return to MUSC.
- You will be given a daily checklist to record the date and time of each SinuSonic use.
- You will be asked to gauge your nasal symptoms using a Visual Analog Scale (VAS).
- After two weeks, you will receive an additional assessment where you will gauge the level of nasal obstruction, any improvements to breathing, ability to smell, pain levels, and any other discomfort in addition to a PNIF test.
- You will be asked to complete the SNOT-22 questionnaire, a questionnaire that consists of 22 questions related to the symptoms of nasal condition and how you feel about it. This questionnaire takes approximately 5 minutes to complete.
- You will be asked to complete at Total Nasal Symptom Score (TNSS) questionnaire. A TNSS questionnaire is used to measure congestion symptom severity. This questionnaire will take approximately 5 minutes to complete.
- You will be asked to complete a Nasal Obstruction and Septoplasty Effectiveness Scale (NOSE Scale). The NOSE Scale is used to show impact of nasal obstruction on your quality of life. This questionnaire will take approximately 3 minutes.
- A nasal rhinoscopy will be performed.
- You will be asked to use the SinuSonic device at home for an additional two weeks.
- The second assessment will last for no more than 1 hour.

Visit 3 (Final Assessment)

- The final assessment will be done through email.
- You will be asked to complete a NOSE Scale.

- You will be asked to complete the SNOT-22 questionnaire.
- You will be asked to complete at TNSS questionnaire.
- This final assessment should take no more than 1 hour.

Participants should not modify the use of any sinonasal medication (Flonase, Nasonex,..) during the study duration.

C. DURATION

Participation in this study will consist of a baseline visit to evaluate for exclusion criteria in addition to 3 assessments over the course of approximately 6 weeks. Each visit will take no more than 1 hour. The final assessment will take place online using email while all other assessments will take place in the Outpatient Sinus clinic on the first floor of Rutledge Tower at MUSC.

D. RISKS AND DISCOMFORTS

CONFIDENTIALITY

There is a risk of a loss of confidentiality of your personal information as a result of participation in this study.

OTHER DISCOMFORTS (Occurrence Rates Unknown)

There are risks to subjects using the SinuSonic device. Subjects may experience a degree of pain due to use of the device. This degree of pain is unknown. There may also be risk of nose bleeds or crusting around the nasal cavity.

The Rhinoscopy may activate the gag reflex (i.e. make you feel like you are choking or going to vomit). Nosebleed, nasal discomfort, spasms, and cough may also occur. Let your study doctor know if you are experiencing any unpleasant symptoms during the procedure. Additionally, this procedure may cause temporary pain or discomfort. Your study doctor will do his/her best to minimize any discomfort you may feel.

UNKNOWN RISKS TO PREGNANT WOMEN, EMBRYO, FETUS OR NURSING INFANT

Use of SinuSonic may involve unknown risks to a pregnant woman, an embryo, fetus (unborn baby), or nursing infant. Therefore, if you are pregnant, planning to become pregnant during the course of this study or are lactating (producing breast milk), (including breastfeeding a child), you cannot participate in this study.

E. MEDICAL RECORDS

If you are an MUSC patient, you have an MUSC medical record. If you have never been an MUSC patient, a MUSC medical record will be created for the purposes of this study. Results of research tests or procedures will be included in your MUSC medical record. All information within your medical record can be viewed by individuals authorized to access the record We will make every effort to keep confidential all research information in the medical record that identify you to the extent allowed by law.

F. BENEFITS

This study is for research purposes only. There is no direct benefit to you from your participation in the study. Information learned from the study may help other people in the future.

G. COSTS

There will be no additional costs to you as a result of being in this study. However, routine medical care for your condition (care you would have received whether or not you were in this study) will be charged to you or your insurance company. You may wish to contact your insurance company to discuss this further. It is possible that your insurance company will refuse to pay for the costs associated with study participation, in which case you will be held financially responsible. Please ask Dr. Zachary M. Soler if you would like to know more about which tests and studies are being done solely for research purposes.

H. PAYMENT TO PARTICIPANTS

You will receive $50 per visit for participation and travel expenses, for a maximum of $150 for three study visits. You will receive a check within four weeks after completion of each visit. You will be reimbursed only for visits which you have completed.

Payments that you receive from MUSC for participating in a research study are considered taxable income per IRS regulations. Payment types may include, but are not limited to: checks, cash, gift certificates/cards, personal property, and other items of value. If the total amount of payment you receive from MUSC reaches or exceeds $600.00 in a calendar year, you will be issued a Form 1099.

I. ALTERNATIVES

Your alternative to taking part in this study is to receive standard medical care as prescribed by your doctor. The following treatments are available for nasal congestion:

• nasal corticosteroid spray

• oral corticosteroids such as prednisone

• nasal saline

Your study doctor will be able to discuss alternative procedure(s) or treatment(s) that may be available, and their potential benefits and risks.

J. DATA SHARING

Information about you (including your identifiable private information and/or any identifiable biospecimens) may have all of your identifiers removed and used for future research studies or distributed to other researchers for future research without additional informed consent from you or your legally authorized representative.

Records of your participation in this study will be held confidential except as disclosure is required by law or as described in this form. Disclosures required by law may include: suspected child abuse; infectious disease; expression of suicidal ideas; those situations in which research documents are ordered to be produced by a court of law; and those situations in which researchers are required to report to the appropriate authorities. Therefore, absolute confidentiality cannot be guaranteed. If the results of this study are published or presented at meetings, you will not be identified.

K. DISCLOSURE OF RESULTS

Clinically relevant research results and individual research results will not be disclosed to you.

L. AUTHORIZATION TO USE AND DISCLOSE (RELEASE) MEDICAL INFORMATION

As part of this research study, your study doctor and his/her research team will keep records of your participation in this study.

The health information MUSC may use or disclose (release) for this research study includes information in your medical record, results of physical exams, medical history, lab tests or certain health information indicating or relating to your condition.

Your study doctor and his/her research team will use and disclose (release) your health information to conduct this study. The health information listed above may be used by and/or disclosed (released) to the following, as applicable:

- The sponsor of the study including its agents such as data repositories or contract research organizations monitoring the study;
- Other institutions and investigators participating in the study;
- Data Safety Monitoring Boards;
- Accrediting agencies;

- Clinical staff not involved in the study whom may become involved if it is relevant;
- Parents of minor children if less than 16 years old. Parents of children 16 years old or older require authorization from the child; or
- Health insurer or payer in order to secure payment for covered treatment;
- Federal and state agencies and MUSC committees having authority over the study such as:

    - The Institutional Review Board (IRB) overseeing this study; Committees with quality improvement responsibilities; Office of Human Research Protections; Food and Drug Administration; National Institutes of Health or Other governmental offices, such as a public health agency or as required by law.

Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them. You do not have to sign this consent form. If you choose not to sign, it will not affect your treatment, payment or enrollment in any health plan or affect your eligibility for benefits. However, you will not be allowed to be a participant in this research study.

You will be given a copy of this consent form. Your authorization will expire at the conclusion of this study or, if you are participating in a study designed for the development of a drug or device, your authorization will remain in effect until the drug or device is approved by the FDA or until the company's application to study the drug/device is withdrawn. You have the right to withdraw your agreement at any time. You can do this by giving written notice to your study doctor. If you withdraw your agreement, you will not be allowed to continue participation in this research study. However, the information that has already been collected will still be used and released as described above. You have the right to review your health information that is created during your participation in this study. After the study is completed, you may request this information.

Your health information will be used or disclosed when required by law. Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury or disability and for conducting public health surveillance, investigations or interventions. No publication or public presentation about the research study will reveal your identity without another signed authorization from you.

If you have questions or concerns about this Authorization or your privacy rights, please contact MUSC's Privacy Officer at (843) 792-8740.

Regulations require that you be given a copy of the MUSC Notice of Privacy Practices (NPP) describing the practices of MUSC regarding your health information. One can be found at the end of this form.

M. SIGNIFICANT NEW FINDINGS

If there are significant new findings during the course of the study, you will be notified.

N. STUDENT PARTICIPATION

Your participation or discontinuance will not constitute an element of your academic performance, nor will it be a part of your academic record at this Institution.

O. EMPLOYEE PARTICIPATION

Your participation or discontinuance will not constitute an element of your job performance or evaluation, nor will it be a part of your personnel record at this Institution.

P. CLINICAL TRIALS.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.

Q. SPONSOR COMMITMENT

In the event a study participant requires medical treatment for a physical illness or injury, Sponsor shall reimburse the Institution or other emergency care provider for the reasonable and necessary costs associated with the immediate treatment of the physical illness or injury sustained as a direct result of taking the investigational compound or undergoing a procedure required by the Protocol, provided that such illness or injury does not arise out of the negligence, willful misconduct, breach of this Agreement, Applicable Law or failure to follow and comply with the Protocol by the Institution, Principal Investigator, the Study Staff, or their employees ("Covered Illness or Injury"). Reimbursement by Sponsor for a Covered Illness or Injury or otherwise shall be limited to those costs not covered by such Study participant's insurance, **excluding** government entitlement programs such as Medicare or Medicaid, For government entitlement programs such as Medicare or Medicaid, the Sponsor will provide reimbursement for all costs related to the Covered Illness or Injury.

R. COLLECTION OF SPECIMENS

If applicable, you will be given a pregnancy test.

S. FUTURE CONTACT

The researcher in charge of this study might like to contact you in the future about other research opportunities. Please initial by your choice below:

____Yes, I agree to be contacted

____No, I do not agree to be contacted

Results of this research will be used for the purposes described in this study. This information may be published, but you will not be identified. Information that is obtained concerning this research that can be identified with you will remain confidential to the extent possible within State and Federal law. The sponsor and the Food and Drug Administration (FDA) will receive copies of the research records. The investigators associated with this study, employees of the sponsor, the FDA, and the MUSC Institutional Review Board for Human Research will have access to identifying information. All records in South Carolina are subject to subpoena by a court of law.

In the event of a study related injury, you should immediately go to the emergency room of the Medical University Hospital, or in case of an emergency go to the nearest hospital, and tell the physician on call that you are in a research study. They will call your study doctor who will make arrangements for your treatment. If the study sponsor does not pay for your treatment, the Medical University Hospital and the physicians who render treatment to you will bill your insurance company. If your insurance company denies coverage or insurance is not available, you will be responsible for payment for all services rendered to you.

T. VOLUNTARY PARTICIPATION/WITHDRAWAL

Your participation in this study is voluntary. You may refuse to take part in or stop taking part in this study at any time. You should call the investigator in charge of this study if you decide to do this. The data collected on you to this point remains part of the study database and may not be removed. Your decision not to take part in the study will not affect your current or future medical care or any benefits to which you are entitled.

The investigators and/or the sponsor may stop your participation in this study at any time if they decide it is in your best interest. They may also do this if you do not follow the investigator's instructions.

Volunteers Statement

I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. If I have any more questions about my participation in this study or study related injury, I may contact Dr. Zachary M. Soler at (843) 792-7165. I may contact the Medical University of SC Patient and Family Care Liaison (843) 792-5555 concerning medical treatment.

If I have any questions, problems, or concerns, desire further information or wish to offer input, I may contact the Medical University of SC Institutional Review Board for Human Research IRB Manager or

the Office of Research Integrity Director at (843) 792-4148. This includes any questions about my rights as a research subject in this study.

I agree to participate in this study. I have been given a copy of this form for my own records.

Signature of Person Obtaining Consent Date *Name of Participant

Signature of Participant Date

NOTICE OF PRIVACY PRACTICES

MUSC Organized Health Care Arrangement (OHCA)

THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESSS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.

The Medical University of South Carolina and its affiliates (including but not limited to the Medical University Hospital Authority, MUSC Physicians, and MUSC Physicians Primary Care) participate in a clinically integrated health care setting. As a result of this clinical integration, these organizations function as an Organized Health Care Arrangement (OHCA) as defined by the Health Insurance Portability and Accountability Act (HIPAA). For purposes of this notice, the members of the MUSC OHCA are collectively referred to in this document as "MUSC." W**e collect or receive this information about your past, present or future health condition to provide health care to you, to receive payment for this health care, or to operate the hospital and/or clinics.**

HOW WE MAY USE AND RELEASE YOUR PROTECTED HEALTH INFORMATION (PHI)

A. The following uses do NOT require your authorization, except where required by SC law:

1. For treatment. Your PHI may be discussed by caregivers to determine your plan of care. For example, the physicians, nurses, medical students and other health care personnel may share PHI in order to coordinate the services you may need.

2. To obtain payment. We may use and disclose PHI to obtain payment for our services from you, an insurance company or a third party. For example, we may use the information to send a claim to your insurance company.

3. For health care operations. We may use and disclose PHI for hospital and/or clinic operations. For example, we may use the information to review our treatment and services and to evaluate the performance of our staff in caring for you.

4. For public health activities. We report to public health authorities, as required by law, information regarding births, deaths, various diseases, reactions to medications and medical products.

5. Victims of abuse, neglect, domestic violence. Your PHI may be released, as required by law, to the South Carolina Department of Social Services when cases of abuse and neglect are suspected.

6. Health oversight activities. We will release information for federal or state audits, civil, administrative or criminal investigations, inspections, licensure or disciplinary actions, as required by law.

7. Judicial and administrative proceedings. Your PHI may be released in response to a subpoena or court order.

8. Law enforcement or national security purposes. Your PHI may be released as part of an investigation by law enforcement.

9. Uses and disclosures about patients who have died. We provide coroners, medical examiners and funeral directors necessary information related to an individual's death.

10. For purposes of organ donation. As required by law, we will notify organ procurement organizations to assist them in organ, eye or tissue donation and transplants.

11. Research. We may use your PHI if the Institutional Review Board (IRB) for research reviews, approves and establishes safeguards to ensure privacy.

12. To avoid harm. In order to avoid a serious threat to the health or safety of a person or the public, we may release limited information to law enforcement personnel or persons able to prevent or lessen such harm.

13. For workers compensation purposes. We may release your PHI to comply with workers compensation laws.

14. Marketing. We may send you information on the latest treatment, support groups and other resources affecting your health.

15. Fundraising activities. We may use your PHI to communicate with you to raise funds to support health care services and educational programs we provide to the community. You have the right to opt out of receiving fundraising communications with each solicitation.

16. Appointment reminders and health-related benefits and services. We may contact you with a reminder that you have an appointment.

B. You may object to the following uses of PHI:

1. Hospital directories. Unless you object, we may include your name, location, general condition and religious affiliation in our patient directory for use by clergy and visitors who ask for you by name.

2. Information shared with family, friends or others. Unless you object, we may release your PHI to a family member, friend, or other person involved with your care or the payment for your care.

3. **Health plan.** You have the right to request that we not disclose certain PHI to your health plan for health services or items when you pay for those services or items in full.

C. Your prior written authorization is required (to release your PHI) in the following situations:

You may revoke your authorization by submitting a written notice to the privacy contact identified below. If we have a written authorization to release your PHI, it may occur before we receive your revocation

1. Any uses or disclosures beyond treatment, payment or healthcare operations and not specified in parts A & B above.

2. Psychotherapy notes.

3. Any circumstance where we seek to sell your information.

WHAT RIGHTS YOU HAVE REGARDING YOUR PHI

Although your health record is the physical property of MUSC, the information belongs to you, and you have the following rights with respect to your PHI:

A. The Right to Request Limits on How We Use and Release Your PHI. You have the right to ask that we limit how we use and release your PHI. We will consider your request, but we are not always legally required to accept it. If we accept your request, we will put any limits in writing and abide by them except in emergency situations. Your request must be in writing and state (1) the information you want to limit; (2) whether you want to limit our use, disclosure or both; (3) to whom you want the limits to apply, for example, disclosures to your spouse; and (4) an expiration date**.**

B. The Right to Choose How We Communicate PHI with You. You have the right to request that we communicate with you about PHI in a certain way or at a certain location (for example, sending information to your work address rather than your home address). You must make your request in writing and specify how and where you wish to be contacted. We will accommodate reasonable requests.

C. The Right to See and Get Copies of Your PHI. You have the right to inspect and receive a copy of your PHI (including an electronic copy), which is contained in a designated record set that may be used to make decisions about your care. You must submit your request in writing. If you request a copy of this information, we may charge a fee for copying, mailing or other costs associated with your request. We may deny your request to inspect and receive a copy in certain very limited circumstances. If you are denied access to PHI, you may request that the denial be reviewed.

D. The Right to Get a List of Instances of When and to Whom We Have Disclosed Your PHI. This list may not include uses such as those made for treatment, payment, or health care operations, directly to you, to your family, or in our facility directory as described above in this Notice of Privacy Practices. This list also may not include uses for which a signed authorization has been received or disclosures made more than six years prior to the date of your request.

E. The Right to Amend Your PHI. If you believe there is a mistake in your PHI or that a piece of important information is missing, you have the right to request that we amend the existing information or add the missing information. You must provide the request and your reason for the request in writing. We may deny your request in writing if the PHI is correct and complete or if it originated in another facility's record.

F. The Right to Receive a Paper or Electronic Copy of This Notice: You may ask us to give you a copy of this Notice at any time. For the above requests (and to receive forms) please contact: Health Information Services (Medical Records), Attention: Release of Information / 169 Ashley Avenue / MSC 369 / Charleston, SC 29425. The phone number is (843) 792-3881.

G. The Right to Revoke an Authorization. If you choose to sign an authorization to release your PHI, you can later revoke that authorization in writing. This revocation will stop any future release of your health information except as allowed or required by law.

H. The Right to be Notified of a Breach. If there is a breach of your unsecured PHI, we will notify you of the breach in writing.

HEALTH INFORMATION EXCHANGES
MUSC, along with other health care providers belongs to health information exchanges. These information exchanges are used in the diagnosis and treatment of patients. As a member of these exchanges, MUSC shares certain patient health information with other health care providers. Should you require treatment at another location that is a part of one of these exchanges, that provider may gather historical health information to assist with your treatment. You have the option of saying that this cannot be done. If you choose not to take part in these alliances, please contact the MUSC Privacy Office at 792-4037.

HOW TO COMPLAIN ABOUT OUR PRIVACY PRACTICES
If you think your privacy rights may have been violated, or you disagree with a decision we made about access to your PHI, you may file a complaint with the office listed in the next section of this Notice. **Please be assured that you will not**

be penalized and there will be no retaliation for voicing a concern or filing a complaint. We are committed to the delivery of quality health care in a confidential and private environment.

PERSON TO CONTACT FOR INFORMATION ABOUT THIS NOTICE OR TO COMPLAIN ABOUT OUR PRIVACY PRACTICES

If you have any questions about this Notice or any complaints about our privacy practices please call the Privacy Officer (843) 792-4037, the Privacy Hotline (800) 296-0269, or contact in writing: HIPAA Privacy Officer / 169 Ashley Avenue / MSC 332 / Charleston SC 29425. You also may send a written complaint to the Office of Civil Rights. The address will be provided at your request.

CHANGES TO THIS NOTCE

We reserve the right to change the terms of this Notice at any time. We also reserve the right to make the revised or changed Notice effective for existing as well as future PHI. This Notice will always contain the effective date. You may view this notice and any revisions to it at: http://www.musc.edu/privacy.

EFFECTIVE DATE OF THIS NOTICE

This Notice went into effect on April 14, 2003.
Revised September 2013.