MC19C1 / 19-006677

Rose Geranium in Sesame Oil Nasal Spray as an Agent to Improve Symptoms of Nasal Vestibulitis: A Phase III Double Blinded Randomized Controlled Trial

NCT04620369

Document Date: 10/05/2022

MAYO CLINIC

Name and Clinic Number

Approval Date: **October 5, 2022**
Not to be used after: **October 4, 2023**

RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: MC19C1, Rose Geranium in Sesame Oil Nasal Spray as an Agent to Improve Symptoms of Nasal Vestibulitis: A Phase III Double Blinded Randomized Controlled Trial

IRB#: 19-006677

Principal Investigator: Charles Loprinzi, M.D., and Colleagues

Key Study Information

This section provides a brief summary of the study. It is important for you to understand why the research is being done and what it will involve before you decide. **Please take the time to read the entire consent form carefully and talk to a member of the research team before making your decision.** You should not sign this form if you have any questions that have not been answered.	
It's Your Choice	This is a research study. Being in this research study is your choice; you do not have to participate. If you decide to join, you can still stop at any time. You should only participate if you want to do so. You will not lose any services, benefits or rights you would normally have if you choose not to take part.
Research Purpose	The purpose of this research is to gather information on the safety and effectiveness of rose geranium in sesame oil nasal spray in treating nasal symptoms. You have been asked to take part in this research because you have bothersome nasal symptoms (dryness, discomfort, bleeding, scabbing or sores) and you are currently receiving chemotherapy.
What's Involved	Study participation involves using nasal spray for 2 weeks and reporting symptoms on questionnaires weekly. This study involves a placebo; there is a 50 percent chance that you will receive the placebo (saline nasal spray) instead of rose geranium in sesame oil nasal spray. Placebos are used in research studies to learn if effects seen in research participants are truly from the active study product. There is

	some information that actually supports that the placebo being used in this trial might provide some benefit for your symptoms. If you are assigned to the placebo group, you will have the option to cross over to the rose geranium in sesame oil nasal spray for an additional 2 weeks.
Key Information	Previous experience with the nasal sprays support that they are generally well tolerated. Spraying something up your nose may be mildly uncomfortable. The sprays may cause some nose dripping for a short time after they are administered. The nasal spray(s) will be provided to you at no cost. This study may or may not make your health better. You do not have to participate in the study to receive treatment for your condition. You may choose no treatment or to obtain one or both of the sprays without being in the study.
Learn More	If you are interested in learning more about this study, read the rest of this form carefully. The information in this form will help you decide if you want to participate in this research or not. A member of our research team will talk with you about taking part in this study before you sign this form. If you have questions at any time, please ask us.

Making Your Decision

Taking part in research is your decision. Take your time to decide. Feel free to discuss the study with your family, friends, and healthcare provider before you make your decision. Taking part in this study is completely voluntary and you do not have to participate.

If you decide to take part in this research study, you will sign this consent form to show that you want to take part. We will give you either a printed or electronic copy of this form to keep. A copy of this form will be put in your medical record.

For purposes of this form, Mayo Clinic refers to Mayo Clinic in Arizona, Florida and Rochester, Minnesota; Mayo Clinic Health System; and all owned and affiliated clinics, hospitals, and entities.

MAYO CLINIC

Name and Clinic Number

Approval Date: **October 5, 2022**
Not to be used after: **October 4, 2023**

Contact Information

If you have questions about …	You can contact …
▪ Study tests and procedures ▪ Materials you receive ▪ Research-related appointments ▪ Research-related concern or complaint ▪ Research-related injuries or emergencies ▪ Withdrawing from the research study	**Principal Investigator(s):** Charles Loprinzi, M.D. **Phone:** (507) 284-2511 **Site Investigator(s):** Stephan D. Thome, M.D. (Mankato) Mina Hanna, M.D. (Albert Lea) **Study Team Contact(s):** Mayo Clinic Health System Mankato Amanda O'connor, R.N. **Phone:** (507) 594-2929 Mayo Clinic Health System Albert Lea Danielle Mutschler, R.N. **Phone:** (507) 668-2050 **Institution Name and Address:** Mayo Clinic 200 First Street SW Rochester, MN 55905 Mayo Clinic Health System – Mankato 1025 Marsh Street Mankato, MN 56001 Mayo Clinic Health System – Albert Lea 404 West Fountain Street Albert Lea, MN 56007
▪ Rights of a research participant	**Mayo Clinic Institutional Review Board (IRB)** **Phone:** (507) 266-4000 **Toll-Free:** (866) 273-4681
▪ Rights of a research participant ▪ Any research-related concern or complaint ▪ Use of your Protected Health Information ▪ Stopping your authorization to use your Protected Health Information	**Research Participant Advocate (RPA)** **(The RPA is independent of the Study Team)** **Phone:** (507) 266-9372 **Toll-Free:** (866) 273-4681 **E-mail:** researchparticipantadvocate@mayo.edu

If you have questions about …	You can contact …
▪ Withdrawing from the research study	
▪ Billing or insurance related to this research study	**Patient Account Services** **Toll-Free:** (844) 217-9591

Other Information:
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.

Why are you being asked to take part in this research study?

You are being asked to take part in this research study because you have bothersome nasal (nose) symptoms (dryness, discomfort, bleeding, scabbing or sores) and you are currently receiving chemotherapy.

About 100 people will take part in this research study. The plan is to have about 50 people take part in this study at Mayo Clinic.

Why is this research study being done?

The purpose of this research is to gather information on the safety and effectiveness of rose geranium in sesame oil nasal spray in treating nasal symptoms.

Information you should know

Who is Funding the Study?
The Breast Cancer Research Foundation (BCRF) is funding this research.

Information Regarding Conflict of Interest:
Your healthcare provider may be referring you to this research study. If your healthcare provider is also an investigator on this study, there is the chance that his or her responsibilities for the study could influence his or her recommendation for your participation. If you prefer, your healthcare provider will be happy to refer you to another investigator on the research study team

for you to decide if you want to participate in the study and to see you for the research study activities while you are in the study.

How long will you be in this research study?

You will be in this study for two weeks. If you were assigned to receive the saline spray (placebo), you have the option to switch to the rose geranium spray for an additional two weeks.

What will happen to you while you are in this research study?

Prior to any study procedures being performed, we will ask you to review this consent form and ask any questions you may have. If you agree to participate, you will sign and date this consent form.

If you are eligible for the study, we will assign you by chance (like a coin toss) to the rose geranium in sesame oil group or the nasal isotonic saline spray group (placebo). You and the Principal Investigator can't choose your study group. There is a 50 percent chance that you will receive the placebo (saline nasal spray) instead of rose geranium in sesame oil nasal spray. Placebos are used in research studies to learn if effects seen in research participants are truly from the active study product.

You will have had a physical exam prior to be assigned to your study group which is part of your regular cancer treatment. You will then complete a questionnaire to record your pre-study nasal symptoms.

Once you are given your assigned nasal spray you will administer 1 spray into each nostril twice daily. At the end of weeks 1 and 2 a nurse will call you to check your symptoms and you will also complete questionnaires that record your nasal symptoms and your experience.

After two weeks you will be told if you had the saline spray (placebo) and if you did receive the saline spray you will be given the opportunity to try the rose geranium spray. If you choose to take the rose geranium in sesame oil spray for an additional 2 weeks, you will then need to complete the same weekly questionnaires.

These questionnaires should only take around 5-10 minutes to complete and do not ask intrusive personal questions. We hope that you will answer all of the questions, but you can skip any questions you don't want to answer.

Tests done only for research purposes are not meant to provide clinical information or help care for you. The results are only important for research. Therefore, the results of tests done with your information and samples will not be provided to you. In the rare event that a finding might affect the health of you or your family, we will contact you and you can choose whether to receive or refuse the information. If you decide to follow up and further medical testing or care is needed, the costs will be billed to you or your insurance.

What are the possible risks or discomforts from being in this research study?

Previous experience with these two nasal sprays support that they are generally well tolerated. Spraying something up your nose may be mildly uncomfortable. The sprays may cause some nose dripping for a short time after they are administered. As with any medication, allergic reactions are possible.

In addition, lipoid pneumonia is a potential (but highly unlikely) toxicity.

As with all research, there is a chance that confidentiality could be compromised; however, we take precautions to minimize this risk.

Are there reasons you might leave this research study early?

You may decide to stop at any time. You should tell the Principal Investigator if you decide to stop.

In addition, the Principal Investigator or Mayo Clinic may stop you from taking part in this study at any time:

- If it is in your best interest,
- If you don't follow the study procedures,
- If the study is stopped.

If you leave this research study early, or are withdrawn from the study, no more information about you will be collected; however, information already collected about you in the study may continue to be used.

We will tell you about any new information that may affect your willingness to stay in the research study.

What if you are injured from your participation in this research study?

Where to get help:
If you think you have suffered a research-related injury, you should promptly notify the Principal Investigator listed in the Contact Information at the beginning of this form. Mayo Clinic will offer care for research-related injuries, including first aid, emergency treatment and follow-up care as needed.

Who will pay for the treatment of research related injuries:
Care for such research-related injuries will be billed in the ordinary manner, to you or your insurance. You will be responsible for all treatment costs not covered by your insurance, including deductibles, co-payments and coinsurance.

What are the possible benefits from being in this research study?

This study may or may not make your health better. While doctors hope that taking rose geranium spray will help with nasal symptoms, there is no proof of this yet. We do know that the information from this study will help doctors learn more about rose geranium spray. This information could help future cancer patients with a similar condition compared to yours.

What alternative do you have if you choose not to participate in this research study?

You don't have to be in this study to receive treatment for your condition. Your other choices may include not taking any treatment or obtaining one or both of the study sprays without participating in the study.

Talk to the Principal Investigator or your doctor if you have any questions about any of these treatments or procedures

What tests or procedures will you need to pay for if you take part in this research study?

The nasal spray will be given to you at no cost. This study should not incur any costs outside of your regular clinical care. You and/or your insurance will need to pay for all other tests and procedures that you would have as part of your clinical care, including co-payments and deductibles.

If you have billing or insurance questions call Patient Account Services at the telephone number provided in the Contact Information section of this form.

Will you be paid for taking part in this research study?

You won't be paid for taking part in this study.

Will your information or samples be used for future research?

Your information collected for this study will not be used or shared for future research studies even if the identifiable information such as your name, Mayo Clinic number or date of birth is removed.

How will your privacy and the confidentiality of your records be protected?

Mayo Clinic is committed to protecting the confidentiality of information obtained about you in connection with this research study.

Various methods are used to safeguard confidentiality. Some or all of the following may be used in this study: assigning a specific code or registration number to your data and samples, storing research materials in locked areas, and storage of password-protected data on a computer.

During this research, information about your health will be collected. Under Federal law called the Privacy Rule, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use and share your health information for research and why they may need to do so. Information about you and your health cannot be used in this research study without your written permission. If you sign this form, it will provide that permission (or "authorization") to Mayo Clinic.

Your health information may be collected from:

- Past, present and future medical records.
- Research procedures, including research office visits, tests, interviews and questionnaires.

Your health information will be used and/or given to others to:

- Do the research.
- Report the results.
- See if the research was conducted following the approved study plan, and applicable rules and regulations.

Your health information may be used and shared with:

- Mayo Clinic research staff involved in this study.
- Other Mayo Clinic staff involved in your clinical care.
- Researchers involved in this study at other institutions.
- The sponsor(s) of this study and the people or groups hired by the sponsor(s) to help perform this research.
- The Mayo Clinic Institutional Review Board that oversees the research.
- Federal and State agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health and other United States agencies) or government agencies in other countries that oversee or review research.
- A group that oversees the data (study information) and safety of this research.

How your information may be shared with others:

While taking part in this study, you will be assigned a code that is unique to you, but does not include information that directly identifies you. This code will be used if your study information is sent outside of Mayo Clinic. The groups or individuals who receive your coded information will use it only for the purposes described in this consent form.

If the results of this study are made public (for example, through scientific meetings, reports or media), information that identifies you will not be used.

In addition, individuals involved in study oversight and not employed by Mayo Clinic may be allowed to review your health information included in past, present, and future medical and/or research records. This review may be done on-site at Mayo Clinic or remotely (from an off-site location). These records contain information that directly identifies you. However, the individuals will not be allowed to record, print, or copy (using paper, digital, photographic or other methods), or remove your identifying information from Mayo Clinic.

Is your health information protected after it has been shared with others?

Mayo Clinic asks anyone who receives your health information from us to protect your privacy; however, once your information is shared outside Mayo Clinic, we cannot promise that it will remain private and it may no longer be protected by the Privacy Rule.

We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- Mayo Clinic, the sponsor of this study
- The National Cancer Institute (NCI) and other government agencies, like the Food and Drug Administration (FDA), involved in keeping research safe for people
- The Minnesota Cancer Clinical Trials Network (MNCCTN) for participants enrolled at Mayo Clinic Health System sites

Your Rights and Permissions

Participation in this study is completely voluntary. You have the right not to participate at all. Even if you decide to be part of the study now, you may change your mind and stop at any time. You do not have to sign this form, but if you do not, you cannot take part in this research study.

Deciding not to participate or choosing to leave the study will not result in any penalty. Saying 'no' will not harm your relationship with your own doctors or with Mayo Clinic.

If you cancel your permission for Mayo Clinic to use or share your health information, your participation in this study will end and no more information about you will be collected; however, information already collected about you in the study may continue to be used.

MAYO CLINIC

Name and Clinic Number

Approval Date: **October 5, 2022**
Not to be used after: **October 4, 2023**

You can cancel your permission for Mayo Clinic to use or share your health information at any time by sending a letter to the address below:

Mayo Clinic
Office for Human Research Protection
ATTN: Notice of Revocation of Authorization
201 Building 4-60
200 1st Street SW
Rochester, MN 55905

Alternatively, you may cancel your permission by emailing the Mayo Clinic Research Participant Advocate at: researchparticipantadvocate@mayo.edu .
Please be sure to include in your letter or email:

- The name of the Principal Investigator,
- The study IRB number and /or study name, and
- Your contact information.

Your permission for Mayo Clinic to use and share your health information lasts until the end of this study, unless you cancel it. The study does not end until all data has been collected, checked (or audited), analyzed, and reported. Because research is an ongoing process, we cannot give you an exact date when the study will end. Sometimes this can be years after your study visits and/or activities have ended.

MAYO CLINIC

Name and Clinic Number

Approval Date: **October 5, 2022**
Not to be used after: **October 4, 2023**

Enrollment and Permission Signatures

Your signature documents your permission to take part in this research.

	/ /	: AM/PM
Printed Name	Date	Time

Signature

Person Obtaining Consent

- I have explained the research study to the participant.
- I have answered all questions about this research study to the best of my ability.

	/ /	: AM/PM
Printed Name	Date	Time

Signature