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Fred Hutchinson Cancer Research Center
University of Washington
Seattle Cancer Care Alliance

Consent to Take Part in a Research Study Called:

Prevention of Respiratory Viruses Using Nozin® in Stem Cell Transplant Recipients

Short Title: The "PREV-NOSE Study"

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Emergency Numbers:
SCCA Patients: 24 hours: **(206) 598-8902**
UW Medical Center Patients: Paging Operator: **(206) 598-6190** - ask for Dr. Steven Pergam

Important things to know about this study.

You are invited to participate in a research study. The purpose of this research is how well a nasal antiseptic (called Nozin®) works to prevent viral respiratory infections in patients who have had an allogeneic stem cell transplant.

People who agree to join the study will be asked to attend up to two clinic visits before their transplant. After transplant, visits will be weekly or every other week from the time of transplant until 100 days after transplant. All visits after enrollment can take place over the phone or in-person. Participants using Nozin would apply it with a swab inside the nose three times a day from seven days before transplant until 100 days after transplant. Additional procedures include twice-a-week collection of nasal and oral swab samples and completion of a daily study diary. The daily study diary would be collected by text message using your phone, by email or using a paper diary booklet, depending on what you prefer. Your primary caregiver can assist in the completion of the diaries as needed. If someone is diagnosed with a new respiratory virus during the study, they will be asked to collect an additional 7 days of nasal swabs and to have an extra visit (or phone call).

We do not know if Nozin would help prevent viral respiratory infections. It's possible that it could make people more like to get an infection or could make a person's symptoms worse. Nozin could cause side effects such as redness or irritation around the nose, as described later in this form.

You do not have to join this study. Regardless of whether you participate in the study, you should follow your doctor's standard instructions for preventing respiratory infections after your transplant. We will give you details about the purpose, procedures, risks and possible benefits related to this study. We will explain other choices that you have. We will also give you any other information that you need to make an informed decision about joining this study.

Following is a more complete description of this study. Please read this description carefully. You can ask any questions you want to help you decide whether to join the study. If you join this study, we will give you a signed copy of this form to keep for future reference.

We invite you to join this research study.

We invite you to join this research study because you are scheduled to have an allogeneic stem cell transplant and do not currently have a viral respiratory infection. Up to 50 people will join this study.

Research is not the same as treatment or medical care. The purpose of a research study is to answer scientific questions.

You do not have to be in the study. You are free to say "yes" or "no", or to drop out after joining. If you say "no," you would have no penalty or loss of benefits. Whatever you decide, your regular medical care would not change.

Why are we doing this study?

We are doing this study to evaluate Nozin, a nasal sanitizer®. We want to know if Nozin may help to prevent viral respiratory infections in patients who have had allogeneic stem cell transplants. We also want to see whether transplant patients have any side effects from using Nozin for 100 days after their transplant. Nozin can be bought in stores. It is also used in hospitals to prevent spread of bacterial infections. Nozin is made from alcohol, ingredients to soothe the skin inside the nose, and preservatives. Nozin has not been tested to see if it is effective in preventing viral respiratory infections.

There are two groups of participants in this study. All participants would follow the same schedule of clinic visits, take swab samples from inside their nose and mouth and keep a daily study diary. One group will be asked to apply Nozin by swabbing the inside their nose three times a day until 100 days after their transplant. The other group will not use Nozin. At the end of the study we will compare the results of tests on the swab samples and review study diaries to see if there is any difference in viral respiratory infections between the two groups.

A computer will randomly assign you (like flipping a coin) to one of the study groups. You would not be allowed to choose which group you are in. You would have a 50% chance of being in the group using Nozin. That means 25 of the total 50 participants will be assigned to the Nozin group.

What research tests, procedures, and treatments are done in this study?

If you consent to participate in this study, we would do these tests and procedures:

Clinic Visits	**Enrollment Visit** *(1 visit)*	**Follow-up Visits** *(10 visits or phone calls)*	**Possible Additional Visit(s)**
Timing:	Within two weeks before transplant	Every week for 6 weeks, then every other week until Day 100	When/if a sample tests positive for a respiratory virus
ALL STUDY PARTICIPANTS			
Review and confirm study eligibility	•		
Randomization to a study group	•		
Questions about medical history and participant background	•		
Training on how to collect swab samples and complete daily diary	•		
Review diary and any respiratory virus symptoms		•	•
Return swab samples taken at home		•	•
ADDITIONAL FOR PARTICIPANTS IN NOZIN GROUP			
Training on how to use Nozin and complete Nozin daily diary pages	•		

In addition to the clinic visits, from the time you enroll until 100 days after your transplant, you would be asked to do the following at home:

ALL STUDY PARTICIPANTS	
Collect nasal swab samples (three)	Twice a week
Collect oral swab sample (one)	Twice a week
Complete study diary for sample collection and respiratory virus symptoms	Daily
ADDITIONAL FOR PARTICIPANTS IN NOZIN GROUP	
Apply Nozin by swab inside your nose, 3 times a day	Daily, 3 times a day
Complete additional diary questions for Nozin	Daily
ADDITIONAL FOR PARTICIPANTS DIAGNOSED WITH A NEW RESPIRATORY VIRUS	
Collect nasal swab samples (one)	Daily for 7 days

How long would you stay in this study?

If you join this study, your participation would begin up to two weeks before your transplant and would last until about 100 days after your transplant. The procedures in the tables above (including use of Nozin, if you are assigned to the Nozin group) last for the full period you are in the study.

Doctors could take you out of this study at any time. This may happen if:

- They think it is in your best interest not to continue in the study.
- You are not able or willing to follow study procedures, including missing more sample collections or doses of Nozin than are allowed.
- If you get mucositis (inflamed surfaces in your nose and/or mouth). This is a common condition after stem cell transplant.
- The whole study is stopped.

If you withdraw from the study for any reason, previously collected information would remain in the study records and would be included in the analysis of results. This information could not be removed from the study records.

If you drop out of the study, may still ask you to return your study diary and any samples collected before you decided to drop out, but you would be free to say no.

What are the side effects (risks)?

In this part of the consent form, we describe the side effects we expect from the sample collection procedures and from Nozin.

If you join this study, we would tell you if we discover new side effects that could affect you.

Inserting swabs into your nostrils to collect samples or to apply Nozin may cause discomfort, irritation, or a tickling sensation. It could make your eyes water or possibly make you cough. Very rarely, the inside of the nostril may be irritated by the swab, which may cause slight bleeding. If this happens, the swab will be taken out right away, and you will be treated appropriately. If you do get a respiratory infection during the study, using swabs to collect samples or apply Nozin could be more uncomfortable.

For participants assigned to the Nozin group: Nozin has been sold over the counter in stores for around ten years and has been well tolerated. Use of Nozin for a 100 day-duration has not been studied. Nozin contains alcohol, moisturizers, and preservative, so severe side effects are not expected. Nozin could cause side effects or risks which are unforeseen or we do not know about yet. We carefully watch everyone in the study for side effects. We would expect most side effects to go away soon after you stop taking Nozin.

The most common side effect associated with Nozin is irritation or redness inside the nose where it is applied. We do not know what percent of people may experience this. If you get mucositis from your stem cell transplant, use of Nozin could make this more uncomfortable. The study staff may ask you to pause the use of Nozin while you have mucositis.

What are the benefits?

We do not know if this study would help you. The use of Nozin to prevent viral respiratory infections is still investigational and has not been tested with stem cell transplant patients.

Although the study may not benefit you directly, we hope the information we learn will help people prevent viral respiratory infections in the future.

You have other choices besides this study.

You do not have to join this study. You are free to say "yes" or "no". Your regular medical care would not change if you decide to say "no". You could follow standard methods to avoid respiratory infections without joining this study.

Enrollment in this study may exclude you from other research studies.

Protecting Privacy as an Individual and the Confidentiality of Personal Information

If you join this study, some people or organizations might need to look at your medical records and research records for quality assurance or data analysis. They include:

- Researchers involved with this study.
- Global Life Technologies (the sponsor of the study) and their agents
- Institutional Review Boards (IRB), including the Fred Hutchinson Cancer Research Center IRB. An IRB is a group that reviews the study to protect the rights and welfare of research participants.
- Fred Hutchinson Cancer Research Center, the University of Washington, and Seattle Cancer Care Alliance
- The U.S. Office for Human Research Protections, Food and Drug Administration, and other regulatory agencies as required

Study diaries can be filled out using an online survey link sent by text message, by email or by completing a paper booklet. The information that you provide through the diary will be stored in a secured online database. Only approved study staff will have access to the database.

We will do our best to keep personal information confidential. But we cannot guarantee total confidentiality. Personal information may be given out if required by law. Such cases are rare. Fred Hutch or our research team may need to contact you in the future for administrative reasons.

We will not use any information that could identify you in any reports about this study, such as journal articles or presentations at scientific meetings.

A description of this clinical trial may be posted on *http://www.ClinicalTrials.gov*. This website will not include information that can identify you. At most, the website will include a summary of the study results. You can search this website at any time.

If you join this study, information about your participation would be made part of your permanent medical record. This information would include a copy of this consent form. If an insurance

company or employer or anyone else were authorized to see your medical record, they would see a copy of this consent form.

Would we pay you if you join this study?

We will pay you $10 per completed study visit, after the Pretransplant Visit. There are 10 visits after the Pretransplant Visit, so this would total $100 if you complete all scheduled visits. We will pay you when you complete the study.

Would you have extra costs if you join this study?

You would not be billed for the cost of Nozin or for lab tests or procedures that are required only because of your participation in this study. You or your insurance company will have to pay for your usual medical care. If you have any questions, please ask the study doctor or study staff. If you choose to complete the daily diary by text message, you may be billed by your cell phone company for the text messages depending on your plan.

What if you get sick or hurt after you join this study?

For a life-threatening problem, call 911 right away or seek help immediately. Contact your study doctor when the medical emergency is over or as soon as you can.

For all other medical problems or illness related to this research, immediately contact Dr. Pergam or the study coordinator at the number on the first page of this form. They will treat you or refer you for treatment. The sponsor will pay for reasonable costs incurred for the treatment of illness or injuries that are a direct result of your participation in the study. There are no funds to pay you for loss of a job, or other costs to you or your family. State or national law may give you rights to seek payment for some of these expenses.

You or your insurer will be billed for treatment of problems or complications that result from your illness or from standard clinical care.

You would not lose any legal right to seek payment for treatment if you sign this form.

What will my information and/or biological samples be used for?

Your information and swab samples will be used for the purposes of this study. Data and samples may be shared with other researchers as required in order to analyze results of the study or perform laboratory tests. If data or samples are shared, they will be coded to protect your identity.

Your swab samples might help researchers develop new products. This research could be done by for-profit companies. There is no plan to share with you any revenue generated from products developed using your samples.

During this study, if the researchers learn new information that may be important to your general health or to your disease or condition, they will share that information with you.

As part of this study, we may look at the genetics of the viruses and bacteria taken from your samples. If we do this your personal genetic information will be filtered out during the testing process.

Could my samples or information about me be used for future research?

By agreeing to participate in this study, your information or left-over samples could be used for future research studies or sent to other investigators for future research studies without additional consent from you. Data and samples will be stored in a secure location. If we share any information or specimens with other researchers, your name or any information that could identify you would be removed.

These future research studies will be reviewed by an oversight group known as an institutional review board or IRB. The IRB would need to approve the research and would decide if we need to ask you for permission in order to use your data and/or specimens.

Your samples would be used only for research. This research could be done by for-profit companies and might help develop new commercial products. If these products make money, there is no plan to share the money with the participants who donate the samples.

Future research may include genetic testing of the viruses and bacteria in your samples. Your personal genetic information would be filtered out.

Researchers would not report the results of future research to you or your doctors. The research results would not be included in medical records.

If you do not want your left-over samples to be used for future research studies without your consent, you should contact Dr. Pergam at the phone number on the first page of this form or at spergam@fredhutch.org after your participation in the study is complete. We ask that you make your request after participation is complete so we can be certain no more material is required for this study and to help us ensure that all your samples are destroyed.

You would have no penalty for withdrawing your samples from future research and your regular medical care would not change. We could not return left-over samples. We could destroy samples if it is stored with a label identifying who donated it. If identification labels have already been removed from a stored sample, it is not possible to tell who donated it. These samples may still be used for research.

Your rights

- You do not have to join this study. You are free to say "yes" or "no".
- If you get sick or hurt in this study, you do not lose any of your legal rights to seek payment by signing this form.
- During the study, we might learn new information that you need to know. For example, some information may affect your health or well-being. Other information might make you change your mind about being in this study. If we learn these kinds of information, we would tell you.

If you join this study, you would not have to stay in it. You could stop at any time (even before you start). Your regular medical care would not change. You would have no penalty for stopping, but it would be better not to join the study if you think that you would change your mind later. If you decide to drop out, we would want you to tell the study doctor as soon as you are able.

Your responsibilities

If you join this study, you would have some responsibilities.

- Follow the schedule of study visits and procedures
- Take study medications as directed (if you are assigned to the Nozin group)
- Tell us about side effects
- Follow other instructions from the study doctor or staff

For more information

If you have questions or concerns about this study, you could talk to your doctor anytime. Other people you could talk to are listed below.

If you have questions about:	**Call:**	
This study (including complaints and requests for information)	206 667-7538 206 667-7648	Dr. Steven Pergam, MD Sara Marquis, Research Coordinator
If you get sick or hurt in this study	206 667-7538	Dr. Steven Pergam, MD
Your rights as a research participant	206 667-5900	Director of Institutional Review Office, Fred Hutchinson Cancer Research Center (email irodirector@fredhutch.org)
	206 543-0098	Human Subjects Division University of Washington (email hsdinfo@uw.edu)
Your bills and health insurance coverage	206 606-6226	Patient Financial Services, Seattle Cancer Care Alliance
Research and use of your blood or samples or research files	206 667-4728	Data Management Office, Clinical Research Division, Fred Hutch

Emergency Numbers:

SCCA Patients: 24 hours: **(206) 598-8902**

UW Medical Center Patients: Paging Operator: **(206) 598-6190** - ask for Dr. Pergam

SIGNATURES

Please sign below if you:

- have read this form (or had it read to you);
- had the opportunity to ask any questions you have;
- had the opportunity to discuss the research with the person obtaining consent; and
- agree to participate in this study.

Participant *(Age 18 or older)*

Printed Name	*Signature*	*Date*

Researcher's Statement

I have discussed the research study, including procedures and risks, with the person signing above. A copy of the signed consent form will be given to the participant.

Printed Name of Person Obtaining Consent Signature	*Signature*	*Date*

Protocol: 10087
Current version date: 06/24/2019
Previous version date: N/A
Copies to: participant, research file, Data Management

Study Staff: Signed Consent Form MUST be sent to Data Management (within 24 hours)
Fred Hutch, 1100 Fairview Ave N, Mail Stop LF-229