EASTMAN
INSTITUTE FOR ORAL HEALTH

UNIVERSITY of ROCHESTER MEDICAL CENTER
MEDICINE of THE HIGHEST ORDER

CONSENT FORM

NCT03663231

Duration of effect of moisturizing spray in patients with symptomatic dry mouth

Principal Investigator: Ralph Saunders DDS MS

This consent form describes a research study, what you may expect if you decide to take part and important information to help you make your decision. Please read this form carefully and ask questions about anything that is not clear before you agree to participate. You may take this consent form home to think about and discuss with family or friends.

Key Information

This is a study which compares two commercially available agents (medications) for the extent to which they help relieve the feeling of dry mouth. You will not be eligible to participate if you have a dairy allergy. Allergies to any other of the elements of the test agent are believed to be extremely rare but you should check with your physician prior to participation if you have any questions or concerns about this. The study staff will explain this study to you in further detail. Please ask questions about anything that is not clear before you agree to participate. You may take this consent form home to think about and discuss with family or friends.

- Being in this study is voluntary – it is your choice.
- If you join this study, you can change your mind and stop at any time.
- You are being asked to take part in this study because you have indicated that you have symptoms of a dry mouth, and your salivary flow test may reveal that you have low saliva flow.
- The purpose of the study is to determine the duration of effect of a single dose of a widely available oral moisturizing spray to relieve symptoms of a dry mouth, and to compare it to an alternative recommended therapeutic agent .
- Your participation in this study will require up to two sessions lasting up to 3 hours each. Because there must be an interval of 48 hours between the sessions, the duration of your participation will be at least 3 days.
- The procedures will require you to complete assessments, to have your salivary flow measured, and to receive a dose of the moisturizing spray and the alternative agent.

    - The following are risks from participating and you should understand what these mean to you:
        - The most common and most serious risk is mild discomfort from having a dry mouth during the study.
        - Breach of confidentiality. You should discuss these risks in detail with the study team.
    - You will not benefit from being in this study.
    - If you choose not to take part, your routine medical and dental care, will not be affected.

Purpose of Study

The primary purpose of this study is to assess the duration of effect of one dose of an over-the-counter moisturizing spray to a therapy commonly recommended by physicians. A secondary purpose is to assess how you perceive your dry mouth related to the actual severity of your low saliva flow in your mouth.

Description of Study Procedures

If you decide to take part in this study, you will be asked to complete a short survey prior to spitting into a cup for 15 minutes to assess your saliva flow. If the results of the assessment of saliva flow indicate that you have a low saliva flow, then you will be eligible to proceed with the study. If your assessment indicates your saliva flow is not low your study participation will end and no further study activities will take place. The results of the saliva flow test will go into your regular dental record.

If the saliva flow test indicates that you are eligible to proceed with the study, you will complete two research visits. Visit 1 will be completed on the same day as the short survey and the saliva flow test.

The full study involves 2 separate visits, each visit taking 3 hours or less. In the first visit, you will be receiving a single dose (3 sprays) of a randomly allocated agent. The moisturizing spray is an over-the-counter product used to help patients manage the discomfort associated with having a dry mouth. The spray consists of starches and oils to restore moisture to the oral tissues as well as flavorings that stimulate salivation. The alternative agent being compared is a non-active standard therapy commonly recommended by dentists and physicians. You will have the opportunity to evaluate each of the agents in this study; however, the order that they will be given will be unknown to you and the investigator.

Visit 1

We will take your vitals and review the medical history included in your dental chart. After initially assessing your level of (dis)comfort due to a dry mouth, you will be randomly administered a dose of a moisturizing agent or alternative agent. You will then be required to indicate your level of (dis)comfort periodically while sitting comfortably in a quiet dimly lit room for up to 2 hours. During this time, you will not be permitted to speak with others or to use your phone in order to minimize potential effects on your saliva flow rate; we recommend, however, that you bring a book or magazine with relaxing content which is unlikely to stimulate a strong emotional response to pass the time. We expect that you may feel discomfort from your dry mouth, and you may interrupt the 2 hour observation period if (i) you feel too dry and need a drink of water or (ii) you feel that the effect of the administered agent has dissipated; otherwise continue for the whole duration. The session will be followed by a questionnaire about your experience.

Visit 2

In 48 hours or more, you will be required to return for a second visit during which your saliva flow will be measured again. However, you will proceed with the study regardless of your level of saliva flow. You will repeat the process as previously described above, although you will be administered a different agent from the one you had in your previous visit. You will be required to indicate your level of (dis)comfort periodically for up to 2 hours. Again, the 2 hour observation period may be interrupted if (i) you feel too dry and need a drink of water or (ii) you feel that the effect of the administered agent has dissipated. Your participation in the full study will end when you complete a questionnaire about your experience.

All parts of the study will take place at the Eastman Institute of Oral Health, 625 Elmwood Avenue, Rochester, NY.

Information about your study participation and study results may be included in your Eastman Dental record. If you have concerns about this or to obtain more detail, you should discuss this with the study team.

Number of Subjects

Approximately 50 subjects will take part in this study. Half of the qualified subjects will randomly receive the moisturizing spray first, while the other half will randomly receive the alternative product first. At a second visit the order of administration of the products will be reversed.

Duration of the Study

Your participation may require two sessions, with up to 3 hours for each the sessions. Because there must be an interval of at least 48 hours between the sessions, the duration of your participation will be at least 3 days but may be as long as six (6) weeks depending on when you are able to schedule the second study visit.

Risks of Participation

As with any study, there is a risk for breach of confidentiality by participating in this study.

The agent being tested is not known to have any long-lasting or permanent effects. Any effects of the product are thought to be easily reversed by rinsing with warm water. If the product inadvertently gets into your eyes or nose it should be rinsed with copious warm water. Prior to administration of the agent, you should close your eyes to minimize this risk. If you believe you are having an allergic reaction to the product, you are encouraged to rinse out the product with warm water while the investigator evaluates the need for emergency assistance. The product being investigated in this study is lawfully marketed in the United States and other countries for relieving the discomfort of a dry mouth.

Should emergency assistance be needed, the Eastman Institute for Oral Health has its own Medical Emergency Response Team, which includes registered nurses who are trained to provide diphenhydramine, epinephrine and other treatments if necessary. If the emergency situation requires additional assistance, the investigator will call 911.

The study team may be notified if you receive other health care services at URMC or its affiliates (e.g., visit to the emergency room). In addition, the following individuals may know you participated in research and may see results of testing conducted for this study:

- Staff at the University of Rochester Medical Center and its Affiliates (e.g., Strong Memorial Hospital, Highland Hospital, URMC primary care, specialist physician offices) who have a reason to access your electronic health record.
- Individuals who request a copy of information from your health record for activities such as treatment or payment (e.g., medical insurance companies, worker's compensation).

Benefits of Participation

You will not benefit from being in this research study.

Sponsor Support

The University of Rochester is receiving departmental funding to support this research study.

Costs
There will be no cost to you to participate in this study.

Payments
You will be compensated $25 for completing the screening activities, which include completing a short survey and a saliva flow test. You will receive this amount whether or not you are found to be eligible and complete the second study visit. If you are eligible and continue with the rest of the study, you will receive an additional $50 upon completing the second study visit for a possible total of $75. If you park in the hospital parking garage, we will also provide you with a free parking pass at each visit. You will not receive any money that may result from any commercial tests or products that are developed as a result of this study.

Confidentiality of Records and Authorization to Use and Disclose Information for Research Purposes

The University of Rochester makes every effort to keep the information collected from you private. In order to do so, we will keep all records in password-protected and encrypted computer files. Sometimes, however, researchers need to share information that may identify you with people that work for the University, regulators or the study sponsor.

If you have never received a copy of the University of Rochester Medical Center (URMC) and Affiliates Notice of Privacy Practices, please ask the investigator for one.
What information may be used and given to others?
The study doctor will get your personal and medical information. For example:

- Research records
- Records about phone calls made as part of this research
- Records about your study visits

Who may use and give out information about you?

- The study doctor and the study staff
- URMC and Affiliates

Your information may be given to:

- The Department of Health and Human Services
- The University of Rochester Institutional Review Board.
- The U.S. Food and Drug Administration (FDA) may also need to inspect study records at some point during the study or even after it has been completed. In the event that this should occur, every effort will be made to keep identifying information about you private

Why will this information be used and/or given to others?

- To do the research
- To study the results
- To see if the research was done correctly

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this research study.

May I review or copy my information?
Yes, but only after the research is over.

How long will this permission be valid?
This permission will last indefinitely but the data will be retained by the principal investigator for three (3) years; it will then be discarded.

May I cancel my permission to use and disclose information?
Yes. You may cancel your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. Upon receiving the written notice, the study team will no longer use or disclose your health information and you will not be able to stay in this study. Information that has already been gathered may need to be used and given to others for the validity of the study.

May I withdraw from the study?
Yes. If you withdraw your permission to be in the study, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?
No. There is a risk that your information will be given to others without your permission.

Future Use of Information/Samples
Your information might be distributed or used for future research studies without additional informed consent. All identifiers will be removed before your information is used or distributed.

Circumstances for Dismissal
You may be withdrawn from the study if you do not keep appointments for study visits or if you cannot complete study activities.

New Study Information
If we discover any new information that might make you change your mind about continuing in the study, we will let you know.

Return of Research Results
In general, we will not give you any individual results from your participation in the study. If we find something of urgent medical importance to you, we will inform you, although we expect that this will be a very rare occurrence.

Contact Persons
For more information concerning this research or if you feel that your participation has resulted in any research related injury, emotional or physical discomfort, please contact**:** Ralph Saunders at 585-275-1141.

Please contact the University of Rochester Research Subjects Review Board at 265 Crittenden Blvd., CU 420628, Rochester, NY 14642, Telephone (585) 276-0005 or (877) 449-4441 for the following reasons:

- You wish to talk to someone other than the research staff about your rights as a research subject;
- To voice concerns about the research;
- To provide input concerning the research process;
- In the event the study staff could not be reached.

Voluntary Participation

Taking part in this study is voluntary. You are free not to take part or to withdraw at any time, for whatever reason. No matter what decision you make, there will be no penalty or loss of benefit to which you are entitled. In the event that you do withdraw from this study, the information you have already provided will be kept in a confidential manner.

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RETURN OF INDIVIDUAL RESULTS

At the conclusion of the study (end of the second visit) you will be informed of your saliva flow rate and how it compares to your symptoms of dry mouth. If you wish to learn more about your symptoms of dry mouth and potential treatments, we will refer you to a dentist who is knowledgeable about care of dry mouth.

SIGNATURES / DATES

After reading and discussing the information in this consent form you should understand:

- Why this study is being done;
- What will happen during the study;
- Any possible risks and benefits to you;
- Other options you may have instead of being in the study;
- How your personal information will be protected;
- What to do if you have problems or questions about this study.

Subject Consent

I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I agree to participate in this study. I have received (or will receive) a signed copy of this form for my records and future reference.

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Subject Name (Printed by Subject)

_____ _____

Signature of Subject Date

Person Obtaining Consent

I have read this form to the subject and/or the subject has read this form. I will provide the subject with a signed copy of this consent form. An explanation of the research was given and questions from the subject were solicited and answered to the subject's satisfaction. In my judgment, the subject has demonstrated comprehension of the information. I have given the subject adequate opportunity to read the consent before signing.

_____

Name and Title (Print)

_____ _____

Signature of Person Obtaining Consent Date

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