Hyaluronidase Via LADD Scleroderma-induced Microstomia

NCT05995626

Approved: 9/19/2025

CONSENT FORM
Adult Consent Form

Title of this Research Study

Invitation and Summary

You are invited to be in this research study. Taking part in this research is voluntary. You do not have to take part. For the purposes of this document: "You" can refer to:

- Yourself
- The person for whom you are the Legally Authorized Representative (LAR)
- Your child under the age of 19.

"Organization" can refer to: University of Nebraska Medical Center (UNMC), Nebraska Medicine (NM), University of Nebraska at Omaha (UNO) or Children's Nebraska (CN).

Here is a summary of the purpose, methods, risks, benefits, and alternatives, to help you decide whether or not to take part in the research.

We are doing this study to see if microstomia can be treated with a laser with medication. We are using this treatment when microstomia is caused by scleroderma or a condition that causes the skin to harden.

A CO2 laser will be used to deliver medication. This laser is used to treat many other skin conditions and is FDA approved.

We will use a medication called hyaluronidase that is FDA approved. This medication is commonly used for other skin conditions. The investigator will treat in three separate visits that are 4-8 weeks apart. We will recruit 10 subjects.

After this treatment you may feel pain, redness, swelling, and sensitivity to pain. These discomforts are the same as treatment without medication.

This study may increase what society knows about drugs delivered by a laser. You may have better chewing ability, speech, and mouth hygiene. This treatment may also improve your self-image and quality of life.

You can choose not to take part in this study.

Why are you being asked to be in this research study?
You are being asked to be in this study because you are 19 years of age or older and have microstomia that is caused by scleroderma. If you have a known allergy to bee stings or are pregnant or plan to become pregnant you cannot participate in the research study.

We will recruit 10 subjects for this study.

What is the reason for doing this research study?
We are doing this study to see if using a laser for medication delivery can be a better and less painful treatment for microstomia when caused by scleroderma. The laser and medication are each FDA approved. The combination of these treatments has not been studied.

We hope this treatment leads to increased mouth motion, improved hygiene of the mouth, self-esteem, and quality of life.

What will be done during this research study?
You will be treated with hyaluronidase (a medication for various skin conditions) using a laser for treating skin conditions. In order to maintain safety during the laser procedure you will need to remain completely still and wear provided protective equipment to shield your eyes. There are no restrictions for eating and drinking following the laser procedure.

If you are pregnant or become pregnant during the duration of the study, you must contact Dr. Sarah Lonowski to end your participation in the study. There is no need to follow the pregnancy to outcome, however you would not be able to receive laser therapy if pregnant.

Your name, date of birth, race/ethnicity and medical record number will be collected from your medical record. The investigator will repeat this treatment in three separate visits. These sessions will be 4-8 weeks apart. At the beginning of each session before the laser procedure, interincisal distance (IID) measurement and the Mouth Handicap in Systemic Sclerosis (MHISS) score will be assessed to track progression from the last visit. Treatment visits will take 30 minutes. On the first and last visits you will complete a survey about your quality of life with your skin condition.

Three months after your last visit, you will be asked to come back for a follow up visit. Durning this visit you will also complete a follow up survey about quality of life. This visit will take 20 minutes.

What are the possible risks of being in this research study?
The risks of this research are like the usual risks of other laser delivered drug treatment for skin conditions. The usual risks include pain after treatment, redness, swelling, and sensitivity to pain. Additional risks of the use of hyaluronidase administered via CO2 laser sessions are not known. Known risks of hyaluronidase include swelling, hypersensitivity, and increased sensitization at site of treatment.

If you are known to have hypersensitivity to hyaluronidase or any other ingredient in the formula you should not use this drug.

You could have other side effects that we do not know about yet.

What are the possible benefits to you?
You may experience better chewing ability, speech, and mouth hygiene. This treatment may also improve self-image and overall quality of life.

You may not get any benefit from being in this research study.

What are the possible benefits to other people?
This study may improve what society knows about laser delivered treatments for skin conditions.

What are the alternatives to being in this research study?
Instead of being in this research study, you can choose not to take part.

What will being in this research study cost you?
There is no cost to you to be in this research study.

Will you be paid for being in this research study?
You will not be paid to be in this research study.

Who is paying for this research?
This research is being paid for by the Department of Dermatology, of the University of Nebraska Medical Center.

What should you do if you are injured or have a medical problem during this research study?
Your health and safety is our main concern. If you are injured or have a medical problem because of this study call someone listed at the end of this consent form. You can get emergency medical treatment at Nebraska Medicine. You can also go to

your doctor, the nearest emergency room or call 9-1-1.

We have no plans to pay for your treatment or give you any other money or compensation.

Signing this does not mean you have given up any of your legal rights.

How will information about you be protected?
In the course of this research we may collect information about you. This can be things that could be used to find out who you are (like your name, phone number, birthdate, address). We call this "identifiable private information". We will keep this information as confidential as possible.
The information will not be used for other research by us, or by any other researcher.

Who can see information about you?
We also will get medical information about you (like medical record number, medical history, or the results of physical exams, blood tests, x-rays or other medical or research procedures). We call this "protected health information" or PHI. PHI is protected by a law called the HIPAA Privacy Rule. We will collect the smallest amount of PHI that we can. We will keep your PHI as confidential as possible.

By signing this consent form, you are letting us (the researchers listed on this consent form and other people involved in this research at the Organization) have access to your PHI. Your PHI will be used only for the purposes described in the section "What is the reason for doing this research study?"

You can change your mind and tell us to stop collecting your PHI for use in this research at any time by writing to the principal investigator. We can still use the PHI we have already collected. If you tell us to stop collecting your PHI, you will have to stop being in this research.

We may share your PHI with other groups listed below:

- The UNMC Institutional Review Board (IRB)
- Institutional officials designated by the UNMC IRB
- The HHS Office for Human Research Protections (OHRP)
- The Food and Drug Administration (FDA)

The Privacy Rule may not apply to all these groups. Once disclosed outside of UNMC federal privacy laws may no longer protect your PHI. Ask the investigator (or contact the Office of Regulatory Affairs at IRBORA@unmc.edu) if you have

questions.

You are letting us use and share your PHI for as long as the research is going on.

How will results of the research be made available to you during and after the study is finished?
In most cases, the results of the research can be made available to you when the study is completed, and all the results are analyzed by the investigator or the sponsor of the research. The information from this study may be published in scientific journals or presented at scientific meetings, but your identity will be kept strictly confidential.

If you want the results of the study, contact the Principal Investigator at the phone number given at the end of this form or by writing to the Principal Investigator at the following address: slonowski@unmc.edu

What will happen if you decide not to be in this research study?
You can decide not to be in this research study. Deciding not to be in this research will not affect your medical care or your relationship with the investigator or the organization. Your doctor will still take care of you and you will not lose any benefits to which you are entitled.

What will happen if you decide to stop participating once you start?
You can stop being in this research (withdraw) at any time. If you decide to stop being in the research, please let us know. Any research data we have already collected can still be used in the research.

Will you be given any important information during the study?
We will tell you right away if we get any new information that might make you change your mind about being in the study.

What should you do if you have any questions about the study?
We gave you a copy of *"What Do I Need to Know Before Being in a Research Study?"* If you ever have any questions about this study, call the Principal Investigator or anyone else listed on this consent form.

What are your rights as a research participant?
You have rights as a research subject. These rights have been explained in this consent form and in The Rights of Research Subjects that you have been given. If you have any questions concerning your rights, or want to discuss problems,

concerns, obtain information or offer input, or make a complaint about the research, you can contact any of the following:

- The investigator or other study personnel
- Institutional Review Board (IRB)
    - Telephone: (402) 559-6463
    - Email: IRBORA@unmc.edu
    - Mail: UNMC Institutional Review Board, 987830 Nebraska Medical Center, Omaha, NE 68198-7830
- Research Subject Advocate
    - Telephone: (402) 559-6941
    - Email: unmcrsa@unmc.edu

Documentation of informed consent

You are deciding whether to be in this research study. Signing means that:

- You have read and understood this consent form.
- You have had the consent form explained to you.
- You have been given a copy of The Rights of Research Subjects
- You have had your questions answered.
- You have decided to be in the research study.
- You have been told you can talk to one of the researchers listed below on this consent form if you have any questions during the study.
- You will be given a signed and dated copy of this consent form to keep.

Signature of Subject_____ Date_____

My signature certifies that all the elements of informed consent described on this consent form have been explained fully to the subject. In my judgment, the subject possesses the legal capacity to give informed consent to participate in this research and is voluntarily and knowingly giving informed consent to participate.

Signature of Person Obtaining Consent_____
Date_____

Authorized Study Personnel
Principal

* Lonowski, Sarah
phone: 402-559-6128
alt #: 402-559-3825
degree: MD

Secondary
* Wysong, Ashley
alt #: 402-427-4839
degree: MD, MS

Participating Personnel
* Ituarte, Bianca
alt #: 402-559-3825
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Rosa-Nieves, Priscilla
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Lead Coordinator
Wackel, Megan
alt #: 402-559-3243
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Other Coordinator
Kustka, Lucinda
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Robins, Larry
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