Official Title: A Phase III Prospective Randomized Trial of Acupuncture for Treatment of Radiation-Induced Xerostomia in Patients With Head and Neck Cancer
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A Phase III Prospective Randomized Trial of Acupuncture for Treatment of Radiation-Induced Xerostomia in Patients with Head and Neck Cancer

[Insert Site PI Name, Principal Investigator]

This is a clinical trial, a type of research study. Your study doctor will explain the clinical trial to you. Clinical trials include only people who choose to take part. Please take your time to make your decision about taking part. You may discuss your decision with your friends and family. You can also discuss it with your health care team. If you have any questions, you can ask your study doctor for more explanation.

You are being asked to take part in this study because you have xerostomia (dry mouth) caused by radiation treatment which you received in the past for cancer. Previous research has found acupuncture may help reduce dry mouth symptoms related to cancer treatment; however, these have been small studies and further large-scale trials are needed.

Why is this study being done?

The purpose of this study is to determine whether or not acupuncture can improve symptoms related to dry mouth due to head/neck radiotherapy.

This study is being done to find out what effects, good and/or bad, acupuncture has on you and your dry mouth caused by radiation therapy for the treatment of your cancer.

How many people will take part in the study?

About 240 people will take part in this study. *[Insert number of patients to be enrolled at your site.]*

What will happen if I take part in this research study?

If you choose to take part in this study, you will be randomized (as with the toss of a coin) to one of three treatment groups. You may be randomized to the standard of care group (group where usual care for dry mouth is given) or to one of two acupuncture groups. One of the acupuncture treatment approaches has not been studied in a large randomized trial and may not target your symptoms. Each group is equally important in the trial. All groups play an important role in helping to determine if acupuncture helps decrease symptoms of dry mouth.

Standard oral hygiene includes instructions regarding mouth rinses, use of lip balms, use of mild fluoride toothpaste, the importance of adequate oral hydration, and other standard advice which will be provided to you by the research nurse at your location. You should continue with standard oral hygiene throughout the study.

Before you begin the study …

Your study doctor will make sure that you are eligible for the trial. Your doctor can determine this by reviewing your medical record and by asking you questions about the history of your dry mouth and about the current intervention for your dry mouth. The doctor or a delegated research staff will also examine the location where the acupuncture will be performed to ensure the site is healthy for acupuncture intervention if randomized to one of the two acupuncture groups. Once it is determined that you are eligible, you will sign this consent form. You will be then asked to complete a Xerostomia Questionnaire (XQ) that will ask questions about your dry mouth. You will also be asked to complete additional questionnaires including: the MD Anderson Symptom Inventory for Head and Neck Cancer (MDASI-HN) questionnaire, the Functional Assessment of Cancer Therapy (FACT-G), and the Acupuncture Expectancy Scale (AES). The questionnaires will ask you questions about your dry mouth, about your expectations of acupuncture, as well as about other symptoms related to cancer and cancer treatment, such as pain, fatigue and appetite changes. It should take approximately 15-20 minutes to complete all questionnaires.

We will also collect and test your saliva at this time. The collection of your saliva will help us to determine how much saliva you currently produce and if the amount of saliva decreased or increased during the study period or if your saliva had any physical changes like the thickness of it, during the study period. You will be given instructions on how your saliva will be collected. Your saliva will be shipped to MD Anderson for testing. Once the saliva samples have been tested, they will be destroyed.

During the Study …

You will be "randomized" into one of the three study groups described below. Randomization means that you are put into a group by chance. A computer program will place you in one of the study groups. Neither you nor your doctor can choose the group you will be in. You will have an equal (one in three) chance of being placed in any group.

If you are randomized to the Standard of Care Group:

- You will receive usual instructions on the care for your dry mouth.
- You will receive teaching on standard oral hygiene that will include instructions on the use of mouth rinses, the use of lip balms, the use of mild fluoride toothpaste, and the importance of adequate oral hydration (techniques for keeping the mouth moist).
- Other advice may be given to you as well.

At the end of weeks 4, 8, 12 and at 6 months, you will be asked to complete the following:

- Xerostomia Questionnaire (XQ)
- MDASI-HN Questionnaire
- FACT-G Questionnaire
- Saliva collection

This will end your participation in this study.

If you are randomized to the Acupuncture Group 1:

- You will receive the same intervention as the standard of care group.
- In addition, you will receive acupuncture.

Acupuncture is a technique of inserting and manipulating very small, sterile needles made of stainless steel into specific points on the body for the purpose of reducing your sensation of dry mouth. If you are randomized to the acupuncture group 1, you will receive acupuncture twice weekly for four weeks.

At the end of week 4 of the study, you will be asked to complete the following:

- Xerostomia Questionnaire (XQ)
- MDASI-HN Questionnaire
- FACT-G Questionnaire
- AES Questionnaire
- Saliva collection

If your symptoms have improved but are not completely resolved at the end of week 4, you may receive an additional 4 weeks (two sessions per week for a total of 8 additional sessions) of acupuncture treatment. If your symptoms are completely resolved or you have had no improvement at the end of week 4, you will receive no additional acupuncture.

At the end of weeks 8 and 12 of the study, you will be asked to complete the following:

- Xerostomia Questionnaire (XQ)
- MDASI-HN Questionnaire
- FACT-G Questionnaire
- Saliva collection

Six months after your last acupuncture visit, you will be asked to complete the following:

- Xerostomia Questionnaire (XQ)
- MDASI-HN Questionnaire
- FACT-G Questionnaire
- Saliva collection

This will end your participation in this study.

If you are randomized to the Acupuncture Group 2:

- You will receive the same intervention as the standard of care group.
- In addition, you will receive acupuncture at different points on the body than those in group 1.

Acupuncture is a technique of inserting and manipulating very small, sterile needles made of stainless steel into specific points on the body for the purpose of reducing your sensation of dry mouth. Participants in group 2 will receive acupuncture at different points on the body than those in group 1. Acupuncture intervention results will be compared between group 1 and group 2. If you are randomized to group 2, you will receive acupuncture twice weekly for four weeks.

At the end of week 4 of the study, you will be asked to complete the following:

- Xerostomia Questionnaire (XQ)
- MDASI-HN Questionnaire
- FACT-G Questionnaire
- AES Questionnaire
- Saliva collection

If your symptoms have improved but are not completely resolved at the end of week 4, you may receive an additional 4 weeks (two sessions per week for a total of 8 additional sessions) of acupuncture treatment. If your symptoms are completely resolved or you have had no improvement at the end of week 4, you will receive no additional acupuncture.

At the end of weeks 8 and 12 of the study you will be asked to complete the following:

- Xerostomia Questionnaire (XQ)
- MDASI-HN Questionnaire
- FACT-G Questionnaire
- Saliva collection

Six months after your last acupuncture visit, you will be asked to complete the following:

- Xerostomia Questionnaire (XQ)
- MDASI-HN Questionnaire
- FACT-G Questionnaire
- Saliva collection

This will end your participation in this study.

If you were randomized to the standard of care arm or the acupuncture treatment arm that has not been evaluated in a large randomized trial, have completed study participation, and have been taken off study, you will be offered 3 complementary sessions of the other acupuncture treatment approach at no cost. Your acupuncturist(s) and research team will help you schedule the 3 sessions should you choose to have them.

All acupuncture will be done by a trained professional approved for the purposes of this study.

Acupuncture will be performed in the following manner:

- The site where the needle will be inserted will be cleaned with alcohol
- The needles will then be inserted in about 14 places on your body (meaning about 14 needles will be used on you each time)
- The needles will be placed at a standardized depth (approximately 0.1 to 1.0 inch), depending on point location.
- The needles will remain in place for 20 minutes
- All needles will be thrown away after they are removed

We can send copies of your test results to your personal physician. Even if you do not wish to have any of your medical information sent to your physician, you can still participate in this research study.

Do you request that we send important medical findings from your study tests/exams to your personal physician?

[ ] Yes [ ] No _____ Initials

How long will I be in the study?

You will be asked to take part in this study intervention for up to 9 months. Your time in the study may be shorter if you show no response. After you have completed the study intervention, you will be taken off study and no further follow-up will be required.

Can I stop being in the study?

Yes. You can decide to stop at any time. Tell the study doctor if you are thinking about stopping or decide to stop. He or she will tell you how to stop safely.

It is important to tell the study doctor if you are thinking about stopping so any risks from the study intervention can be evaluated by your doctor. Another reason to tell your doctor that you are thinking about stopping is to discuss what follow-up care and testing could be most helpful for you.

The study doctor may stop you from taking part in this study at any time if he/she believes it is in your best interest; if you do not follow the study rules; or if the study is stopped.

What side effects or risks can I expect from being in the study?

You may have side effects while on the study. Everyone taking part in the study will be watched carefully for any side effects. However, doctors don't know all the side effects that may happen. Side effects may be mild or very serious. Your health care team may give you medicines to help lessen side effects. Many side effects go away soon after you stop taking the intervention. In some cases, side effects can be serious, long lasting, or may never go away.

You should talk to your study doctor about any side effects that you have while taking part in the study.

Side effects due to acupuncture are uncommon. Possible risks and side effects related to acupuncture include:

Likely

- Mild Pain including:
- Stinging sensation with needle insertion
- Dull ache around insertion area

Less Likely

- Slight Bruising at needle insertion area
- Minimal Bleeding

Rare but serious

- Infection

Reproductive Risks: There are no known reproductive risks to receiving acupuncture intervention as applied in this study.

For more information about risks and side effects, ask your study doctor.

Are there benefits to taking part in the study?

Taking part in this study may or may not make your health better. While doctors hope acupuncture will be more useful against dry mouth compared to the usual treatment, there is no proof of this yet. We do know that the information from this study will help doctors learn more about acupuncture as an intervention for dry mouth caused by radiation therapy. This information could help future cancer patients.

What other choices do I have if I do not take part in this study?

Your other choices may include:

- Getting treatment or care for your dry mouth without being in a study
- Taking part in another study
- Getting no treatment

If you choose to receive treatment or care for your dry mouth without being in this study, take part in another study, or get no treatment, the potential risks are that your symptoms may not improve or you may experience side effects related to the other treatment approaches you use. Potential benefits are that your dry mouth symptoms could improve from other treatments.

Talk to your doctor about your choices before you decide if you will take part in this study.

What are the costs of taking part in this study?

The acupuncture interventions will be provided at no cost to you while you take part in this study. There may be additional costs associated with the acupuncture interventions that will not be covered, so you or your insurance company may have to pay for this. Please be sure to speak with the acupuncture provider about any additional costs.

Even though it probably won't happen, it is possible that the acupuncture interventions *may* not continue to be provided for some reason. If this would occur, other possible options are:

- You might be able to get the acupuncture interventions, but you or your insurance company may have to pay for it.

If a problem with getting acupuncture interventions occurs, your study doctor will talk to you about these options.

You will not be paid for taking part in this study.

For more information on clinical trials and insurance coverage, you can visit the National Cancer Institute's Web site at **http://cancer.gov/clinicaltrials/understanding/insurance-coverage .** You can print a copy of the "Clinical Trials and Insurance Coverage" information from this Web site.

Another way to get the information is to call 1-800-4-CANCER (1-800-422-6237) and ask them to send you a free copy.

WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed except as authorized by you or as required by law. However, there is always some risk that even de-identified information might be re-identified.

Participant information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

Participant information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

If you choose to participate in this study, your medical record at *[enter your institution's name]* will indicate that you are enrolled in a research study. Information about the research and any medications or devices you are being given as a participant may also be included in your medical record. This part of the medical record will only be available to people who have authorized access to your medical record. If you are not a patient at this Medical Center, a medical record will be created for you anyway to ensure that this important information is available to doctors in case of an emergency.

What happens if I am injured because I took part in this study?

[Enter information per institution policies.]

What About My Health Information?

[Enter information per institution policies.]

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or in the event of a research-related injury, contact the study investigator, *[Include your site PI information here.]*

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at *[Include your site IRB information here.]*

You will be given a copy of this signed consent form.

Where can I get more information?

You may call the National Cancer Institute's Cancer Information Service at: 1-800-4-CANCER (1-800-422-6237)

You may also visit the NCI Web site at http://cancer.gov/

- For NCI's clinical trials information, go to: http://cancer.gov/clinicaltrials/
- For NCI's general information about cancer, go to http://cancer.gov/cancerinfo/

You will get a copy of this form. If you want more information about this study, ask your study doctor.

My Signature Agreeing to Take Part in the Study

I have read this consent form or had it read to me. I have discussed it with the study doctor and my questions have been answered. I will be given a signed copy of this form. I agree to take part in the study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

_____

Participant's signature

_____

Participant's printed name

_____ _____ am/pm

Date of signature Time

_____

Signature of person(s) obtaining informed consent:

_____ _____ am/pm

Date of signature Time