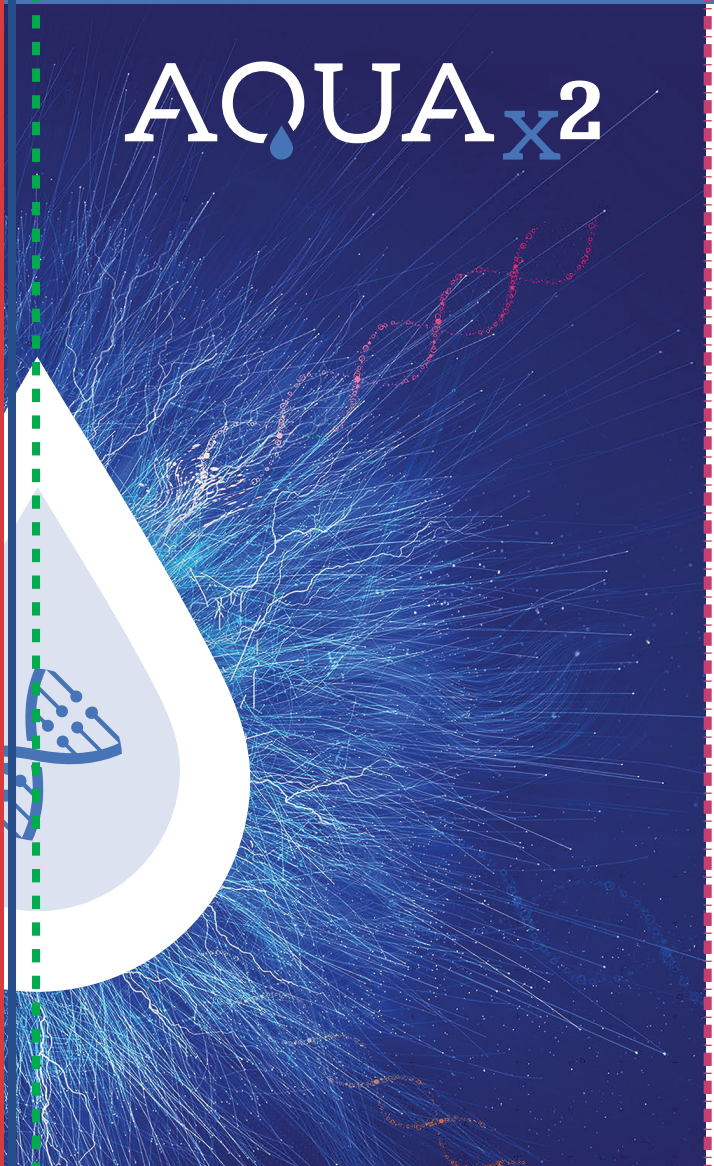
AQUAx2



WHAT ARE CLINICAL RESEARCH STUDIES?

Clinical research studies help doctors and scientists determine whether a medical strategy, drug, or device is safe and effective for humans. Participation in clinical research studies is voluntary, and participants may decide to stop participating at any time without that decision affecting their medical care.

For more information about the AQUAx2 study, visit
https://aquax2study.com

Study Information:
https://clinicaltrials.gov/study/NCT05926765

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MEIRAGTx

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IRB Approved at the Protocol Level
May 28, 2024

Do you have dry mouth?

(also known as xerostomia)

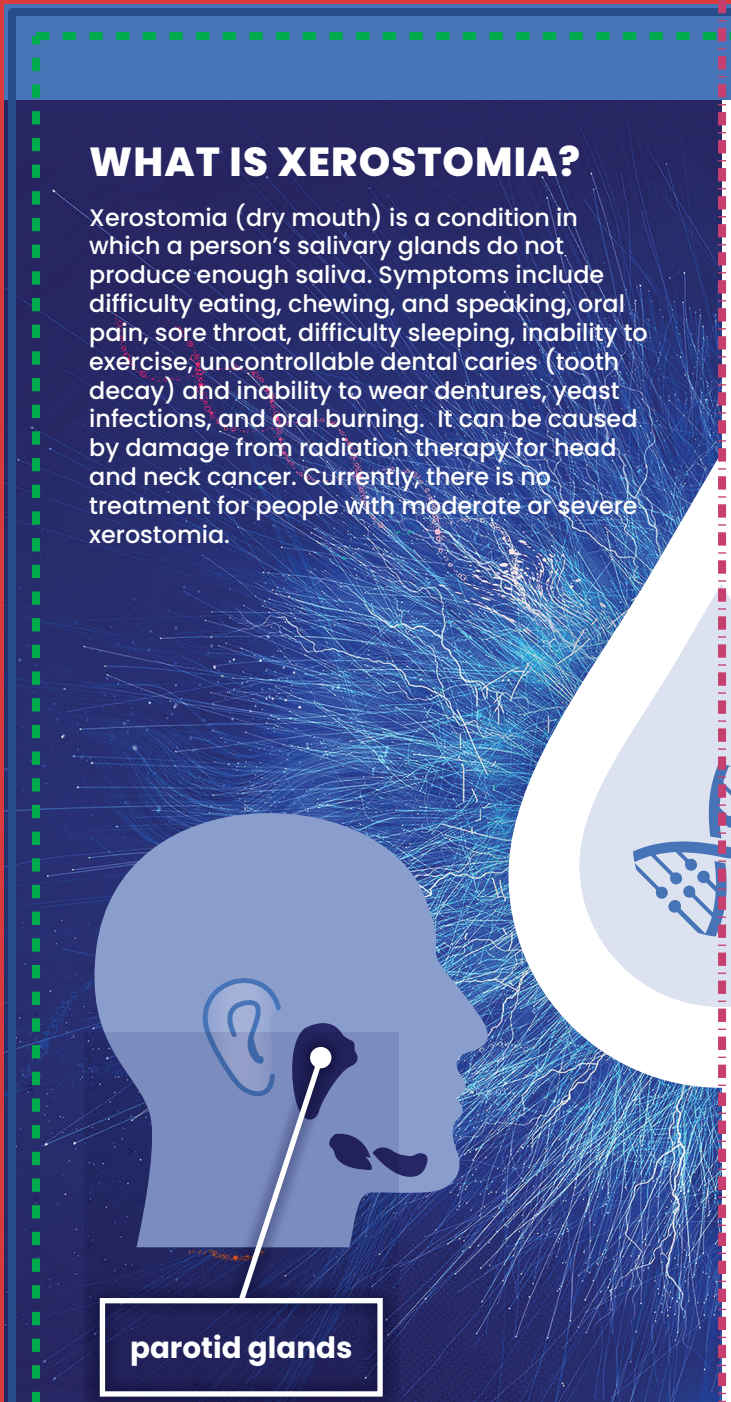
Learn more about the AQUAx2 clinical research study for people with xerostomia resulting from radiation therapy for previous head and neck cancer.

AQUAx2

https://aquax2study.com

WHAT IS XEROSTOMIA?

Xerostomia (dry mouth) is a condition in which a person's salivary glands do not produce enough saliva. Symptoms include difficulty eating, chewing, and speaking, oral pain, sore throat, difficulty sleeping, inability to exercise, uncontrollable dental caries (tooth decay) and inability to wear dentures, yeast infections, and oral burning. It can be caused by damage from radiation therapy for head and neck cancer. Currently, there is no treatment for people with moderate or severe xerostomia.



The parotid glands are a pair of salivary glands located under the skin in front of each ear and extending along the angle of the jaw. Radiation-induced damage to these glands reduces the amount of saliva they make.

WHAT IS THE AQUAx2 STUDY?

The AQUAx2 study is a clinical research study for people with moderate or severe dry mouth (xerostomia) caused by radiation therapy for head and neck cancer. The purpose of this study is to see if the investigational gene therapy, AAV2-hAQP1 (study drug), has an effect on dry mouth symptoms and the amount of saliva produced, and to see if it is safe and well-tolerated in people with dry mouth as a result of receiving radiation therapy for head and neck cancer.

WHAT CAN STUDY PARTICIPANTS EXPECT?

There are 13 study visits. These are comprised of three screening visits to determine eligibility, one dosing visit to receive the gene therapy, and nine follow up visits to monitor health and safety.

If you qualify for the study, you will be randomly assigned to 1 of 3 treatment groups. Two of these groups will receive the study drug (one of two different strengths) and the third a placebo (an inactive solution that does not contain the study drug). If you receive the placebo in this study, you will be offered the active gene therapy in a follow-up study that will start after the AQUAx2 study is completed.

The procedure for administering the study drug takes place in a physician's office or dentist's chair. The participant opens their mouth, the investigator inserts a very small catheter into each parotid salivary gland and then infuses the study drug into the glands. The procedure takes about 15 minutes per side. No anesthesia is needed.

AQUAx2

WHO CAN PARTICIPATE IN THE STUDY?

Study participants must meet certain criteria* to qualify for the study:

1. 18 years old or older
2. It must be at least 3 years since your final radiation treatment
3. You must be suffering from moderate or severe xerostomia
4. You must be free from recurrence of your cancer and never have had another form of cancer
5. You must not have a diagnosis of Sjogren's syndrome, myasthenia gravis or acute angle closure glaucoma
6. You cannot be infected with HIV
7. You cannot have kidney failure
8. You cannot be an active smoker and may not have used any tobacco product (including vaping) in the past 3 years
9. You cannot have uncontrolled diabetes (Hemoglobin A1c >7%)

*Other criteria apply

WHAT IS THE STUDY DRUG?

The study drug delivers a gene designed to make a specific protein that allows water to flow into the parotid ducts and then into the mouth to moisten it.

The study drug is investigational, which means it is still being studied. Regulatory authorities such as the US Food and Drug Administration (FDA), Health Canada, and the Medicines and Health-care Products Regulatory Agency (MHRA) do not currently allow it to be sold as a therapy for xerostomia. These regulatory authorities and central and local ethics committees have approved the conduct of the AQUAx2 trial.