Official Title: Intensive Preventative Dental Program Pilot Study
NCT07218068
IRB Approval Date: 02/14/23

ATRIUM HEALTH
CONSENT TO PARTICIPATE IN A RESEARCH STUDY
AND AUTHORIZATION TO DISCLOSE HEALTH INFORMATION

Sponsor / Study Title: **Atrium Health Department of Oral Medicine / "Intensive Preventative Dental Program (IPDP) Pilot Study"**

Atrium Health Number: **03-21-01A**

Principal Investigator: (Study Doctor) **Michael Brennan, DDS, MHS**

Telephone: [redacted] **(24 hours)**

Address: **Atrium Health**
Department of Oral Medicine
[redacted]

KEY INFORMATION

You are being asked to participate in a research study. Your participation in the study is completely voluntary. If you choose to take part, you will receive fluoride varnish on your teeth every 3 months for the duration of the study to determine if this treatment is beneficial to those who previously received radiation therapy for head and neck cancer.

The duration of your participation in the study will be up to 15 months. To participate in the study, you are expected to attend 2 dental visits and 4 oncology visits. The duration of each dental visit is about 30 minutes. An extra 15 minutes may be added to your standard of care visits with your oncologist for the 4 oncology visits. You will receive payment for completion of each dental visit. There are no costs associated with your participation in the study. You may not or will not receive any benefit from participating in this study; however, the information learned may help others in the future. Risks associated with participation are considered no more than minimal risk. Risks of the study include potential loss of confidentiality and potential dislike of the flavoring of the fluoride varnish.

INTRODUCTION

Dr. Michael Brennan, Dr. Matthew Ward and their associates are asking you to participate in this research study at the Atrium Health Oral Medicine & Maxillofacial Surgery, Atrium Health Dental Clinic (AHDC) and Atrium Health (AH). You are being asked to take part because you will be receiving radiation therapy (x-rays used to kill cancer cells) to treat your head and neck cancer (HNC). The radiation therapy to treat your cancer may cause a dry mouth (low amounts of saliva) from damage to your salivary glands which may increase your risk of cavities (decay) on your teeth.

The consistent use of prescription fluoride on teeth may reduce the development of cavities and tooth loss after radiation therapy for HNC. The purpose of this study is to evaluate the change in the development of cavities or gum problems when prescription fluoride varnish is applied to your teeth every three months during the first year after completion of your radiation therapy. These results will be compared to a previous study's results of patients who did not receive prescription strength fluoride applications after radiation therapy.

Your participation will last for approximately 12 months after completion of your radiation treatments for a total of approximately 15 months of participation.

- If you agree to be in the study, you will have two research specific visits (dental evaluation by trained research staff), the first one will be prior to start of your radiation therapy and the second visit will be approximately 12 months after completion of your radiation therapy. In addition, every three (3) months during the first 12 months after completion of radiation, during your standard oncology visits, you will have a dental exam and a fluoride varnish application completed by your oncology provider. This will be a total of two research visits and four visits during standard of care oncology appointments for a total of six research associated visits.

- This study does not involve a change in standard of care for treatment of your cancer or the follow up with your cancer doctors or dentist. You are encouraged to continue standard of care visits with all of your health care providers, including your dentist.

- This is not a treatment study; the fluoride gel application does not treat your cancer or treat dental cavities. Fluoride is routinely used on teeth to reduce the formation of cavities.

- This study involves the application (4 times) of prescription fluoride varnish routinely used by dentists and applied during standard of care dental visits. Fluoride varnish applications have not been associated with fluoride treatment-related issues.

- The oncologist's oral exam and application of prescription fluoride varnish 4 times during your first year after radiation therapy is not standard of care. Routine post-radiation oncology visits do not involve application of fluoride or specific oral exams.

- Alternatives to help reduce the risk of cavities involves but are not limited to long-term routine brushing with fluoride toothpaste, flossing and routine consistent dental cleanings.

- There is no cost to you for being in this study.

- This study has no known benefits.

- Information collected, directly from you and your medical record, during this research project will include your demographics, medications, medical conditions, cancer treatment and your oral care routine. Information about the health of your teeth and gums and dental visits will be collected during the dental/oral exams.

- You will be one of approximately 40 people involved in this research study.

- Your participation in this study is completely voluntary.

ADDITIONAL/MORE DETAILED INFORMATION

During the two research specific visits, a member of the study team may ask you questions concerning your demographic information, medical and medication history, and oral care routine. During these research specific visits, you will also have a dental examination. At the first research visit (prior to start of radiation therapy) and the last visit (about 12 months after radiation therapy is completed), we may count your teeth, assess for cavities, and record periodontal measurements (using a dental tool to measure the space between your gums and teeth). The dental examination and measurements are like what is done when you visit a dentist for routine care.

During the four routine oncology visits (every three months post radiation) the oncology specialist completes the dental exam and one of the oncology staff will apply fluoride varnish to your teeth (similar to fluoride applications at a dentist office) after the oral exam. After the fluoride application you may be asked to not eat or drink for 30 minutes. During your exam you will also be asked if you had seen a dentist or have any oral/dental pain.

SUBJECT RESPONSIBILITIES/EXPECTATIONS

You will be asked to answer questions about your oral care, social and demographic information, medication history, medical history, and dental history. You will have two research specific visits for which you may be asked to come into the Atrium

Health Dental Clinic or the Atrium Health Oral Medicine & Maxillofacial Surgery, these may last about 30 minutes. The four oncology specialist evaluations will take place during your post-radiation standard of care oncology visits at your oncologist office, you will not be asked to come in separately, however, it may add about 15 minutes to your visit.

RISKS

This study does involve the application of prescription fluoride varnish to your teeth there is minimal risk associated with prescription fluoride applications completed by a trained care provider.

The dental examinations will involve procedures that are routinely done at dental visits. If we record periodontal measurements, you may experience a little discomfort and some gum bleeding and tenderness during and after the examination.

We will collect personal health information from you for this study. We will also collect personal health information from your medical records. There is a small risk associated with the loss of confidentiality with release of information from your medical records. The research team follows strict confidentiality standards to lessen the risk.

There may be other risks of study participation that are not known at this time. If we learn information that might affect your willingness to participate in the study, we will tell you about that information.

EXCLUSION CRITERIA

You will be excluded from the study (not able to participate) if you meet any of the following criteria:

- You are <18 years old
- Have less than four (4) natural teeth
- Not receiving radiation therapy to treat your head and neck cancer
- Not willing to come to the AHDC or Atrium Health Oral Medicine & Maxillofacial Surgery for the two-research specific dental evaluations and participate for the duration of the study
- Not receiving radiation therapy at an AH Oncology site
- Had previous radiation therapy to treat a head and neck cancer

ADDITIONAL COST

There are no costs to you for participating in this study. All procedures will be provided free of charge.

COMPENSATION

As a participant in the study, you will receive a stipend for each scheduled study specific visit that you complete as allowed in the study. You will be paid for study visits that you complete, even if you do not complete the overall study.

You will receive $50 for the two research specific visits that you attend, first one is before you start radiation therapy and the second one approximately 12 months after you complete radiation therapy. You may receive up to $100.00 if you attend both visits.

Greenphire is a company working together with Atrium Health (AH) to manage the study participant payment process. You will be issued a Greenphire ClinCard, which is a debit card that your funds are loaded onto at the completion of each study visit. When a visit is completed, funds will be approved and loaded onto your card. The funds will be available within 2 business days and can be used at your discretion. You will be issued one card for the duration of your participation.

In order for Greenphire to be able to reimburse you via the ClinCard, Greenphire needs to collect certain information about you, including:

name
address
date of birth
email address (optional)
SSN
W9 or W8

All information is stored in a secure fashion on Greenphire's system. Your information will not be shared with any third parties and will be kept completely confidential.

Federal Regulations about payment of research subjects require that you fill out a form called a W-9 form. The W-9 is a tax form that asks for information including your name and Social Security number.

Choosing to complete a W-9 is up to you. If you decide you do not want to complete a W-9 form, you can still be in this study. Choosing not to fill out a W-9 will not harm your relationship with your doctor or Atrium Health.

But if you choose not to complete the W-9 form, you cannot receive any payment.

You do not waive any legal rights by signing this consent form.

WITHDRAWAL

Your participation in this study is completely voluntary. You should not feel pressured to be a part of this study. If you decide not to be in the study, this will not harm your relations with your doctors or with Atrium Health. You are free to stop being in the study if you change your mind after entering it. This would not harm your relations with your doctors or Atrium Health.

We will tell you about new medical findings that may affect your willingness to continue in the study.

CONFIDENTIALITY

The records of this study will be kept private. If any report about this research is published, we will not include any information that will make it possible to identify you. However, there is some risk that de-identified data might be re-identified. Also, your record for this study may be reviewed and/or photocopied by Atrium Health, or by representatives of the Food and Drug Administration or other government agencies.

- Your information collected as part of this research, even if identifiers are removed, could then be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative.

WHAT HAPPENS IF YOU EXPERIENCE AN INJURY OR ILLNESS AS A RESULT OF PARTICIPATING IN THIS STUDY?

Wake Forest University Baptist Medical Center maintains limited research insurance coverage for the usual and customary medical fees for reasonable and necessary treatment of injuries or illnesses to some participants in certain research studies. To the extent research insurance coverage is available under this policy, the reasonable costs of these necessary medical services will be paid, up to a maximum of $25,000. To the extent research coverage is not available, you or your insurance company may be charged for the costs of medical care. You may receive care at Wake Forest University Baptist Medical Center and/or Atrium Health.

If you are injured, the insurer may require information such as your name, social security number, and date of birth in order to pay for your care. This is because the insurer is required by law to report any payments made to cover the care of any persons who are members of a government insurance plan to the Department of Health and Human Services.

You do not give up any legal rights as a research participant by signing this consent form. For more
information on medical treatment for research related injuries or to report a study related illness,
adverse event, or injury you should call Dr. Michael Brennan at [redacted] or if after hours at [redacted].

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AUTHORIZATION TO USE AND DISCLOSE YOUR PROTECTED HEALTH INFORMATION

If you wish to participate in this research study, you

_____

Printed Name of Research Participant

must sign this Authorization. By signing this Authorization, you give all healthcare providers, including Atrium Health, permission to use or disclose (release) your protected health information, both past and present, for the research study described here:

Intensive Preventative Dental Program (IPDP) Pilot Study

The protected health information that we may use or disclose (release) for this research may include all information in your medical record, such as results of physical examinations, medical history, lab tests, or certain health information indicating or relating to a particular condition.

The health information listed above may be used by and/or disclosed (released) to Dr. Brennan and the Study research staff:

- Study doctor and research staff
- Regulatory or other governmental authorities of the United States or other countries based on this study
- Atrium Health employees
- Other persons or agencies as required by law or allowed by federal regulations

- Data coordinating centers that will receive and process PHI; and/or
- Atrium Health Institutional Review Board (Atrium Health IRB) or Data Safety and Monitoring Boards.

Atrium Health is required by law to protect your protected health information. By signing this Authorization, you authorize Atrium Health to use and/or disclose (release) your protected health information for this research study. Those persons who receive your protected health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your protected health information with others without your permission, if permitted by laws governing them. Your protected health information may then no longer be protected by the Privacy Rule.

Please note that you do not have to sign this Authorization, but if you do not, you may not receive research-related treatment through this study. However, Atrium Health may not condition (withhold or refuse) your other Atrium Health providers treating you on whether you sign this Authorization. You may change your mind and withdraw (take back) this Authorization at any time, except to the extent that Atrium Health or the Sponsor has already used or disclosed your protected health information based on this Authorization. To withdraw this Authorization, you must write to the Study Doctor at the address listed on the first page of this form.

No publication or public presentation about the research described above will reveal your identity without another Authorization from you. If all protected health information that does or can identify you is removed, the remaining information will no longer be subject to this Authorization or federal rules (such as the Privacy Rule) and may be used or disclosed for other purposes.

When the research for which the use or disclosure is made involves treatment and is conducted by Atrium Health: To maintain the integrity of this research study, you generally will not have access to your personal health information related to this research until the study is complete.

At the conclusion of the research study and at your request, you generally will have access to your protected health information. Access to your protected health information in a medical record is described in the Notice of Privacy Practices provided to you by Atrium Health.

When conducting research, the data and results may be used or disclosed for further treatment outcomes research or to research a secondary result. This Authorization will remain in effect after the end of the current study, and any future related secondary study unless it is revoked by the you in writing as described above.

_____

Signature of Participant

_____

Printed Name of Participant

_____

Date

FINANCIAL INTEREST OF STUDY DOCTOR

None of the doctors asking you to participate in the study have received or will receive money or other benefits for personal use from this study.

QUESTIONS

The researchers doing the study at Atrium Health are Dr. Michael Brennan, Dr. Matthew Ward and their associates. You may ask them any questions you have now. If you have questions later, you may contact Dr. Brennan at:

Atrium Health
Department of Oral Medicine
[redacted]

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 [redacted] or the Research Subject Advocate at [redacted].

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CONSENT

I have read the above information. I have asked any questions I had, and those questions have been answered. I agree to be in this study and authorize the use of my personal health information. I will receive a signed copy of this form.

Subject Name (Printed): _____

Subject Signature: _____Date: _____Time: _____am pm

Person Obtaining Consent (Printed): _____

Person Obtaining Consent:
_____Date:_____Time:_____am pm