

THE ARMOR TRIAL

Improving Oral Health During Cancer Care

JOIN THE STUDY

For more information on how to be part of the ARMOR Trial, contact the study team at:

(917) 586-9089

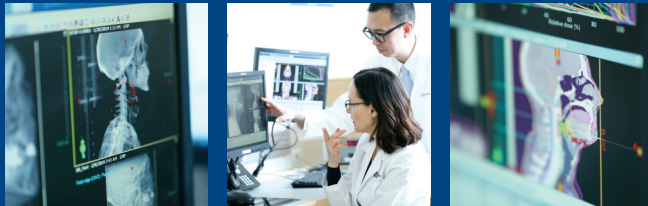
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Improving Oral Health During Cancer Care

Have you recently been diagnosed with head or neck cancer that will be treated with chemoradiation?

If so, you may be eligible to participate in a research study.



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What is the research study?

The ARMOR Trial is a research study for head and neck cancer patients to test whether a new oral health protocol delivered by dental professionals during chemoradiation treatment can prevent the severity of sores in the mouth, a common side effect of chemoradiation therapy.

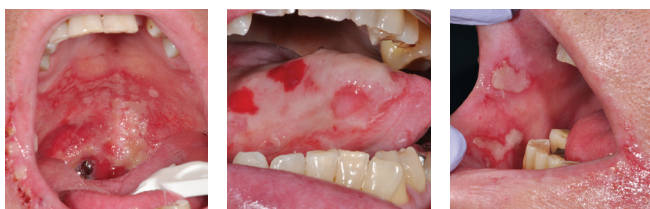
Many individuals receiving chemoradiation develop painful mouth sores and ulcers, a condition called **oral mucositis**.

This inflammation of the mucous membranes in the mouth and throat can cause considerable pain when eating, speaking, or drinking.

There is no widely accepted treatment or prevention for this condition.

This study will test whether oral cleanings performed by dental care providers can delay the onset and reduce the severity and duration of oral mucositis, prevent oral infections that could lead to serious systemic infections, reduce oral pain, and consequently, optimize nutritional support.

Ultimately, researchers hope to improve the quality of life during cancer care.



Oral mucositis is a common side effect of radiation therapy.

How long will I be in the study?

The length of this study will vary depending upon the timing of your chemoradiation as prescribed by your treating physician. The average participant will attend 12 visits over the course of approximately 22 weeks. This study will enroll a total of 120 subjects.

What are the possible risks/discomforts?

There are few minor risks associated with the oral cleaning procedure. You may experience minor pain and irritation during and after the cleaning. These effects should be temporary.

What are the possible benefits of the study?

At this stage of the research, except for a more frequent monitoring of oral health and a professional dental cleaning that participants will receive at baseline, investigators cannot assure that there will be additional direct benefit expected from participation in this study. However, it is hoped the knowledge gained will be of benefit to other cancer patients in the future.

Will I be paid for being in this study?

If you qualify for the study and attend all study visits, you will receive up to \$610 for participation in this study (you must provide your Social Security number).

Will I have to pay for anything?

You will not be charged for any study-related procedures during your participation in this study.

What am I being asked to do?

Screening and Baseline Visits

Prior to starting your cancer treatment, you would attend a screening and baseline visit(s) which will include dental cleaning and fluoride treatment.

Study Treatment Visits

Study visits will occur weekly during your chemoradiation treatment and for approximately 5-9 weeks. Follow up visits will occur 1 and 3 months after completion of chemoradiation treatment. During the first study treatment, you will be randomly assigned to either Group A or Group B.

If you are assigned to Group A, you will receive a standard of care oral health intervention where a dental professional will deliver toothbrushing/flossing plus oral health instructions performed once every week.

If you are assigned to Group B, you will have your teeth brushed by a dental professional and will receive the study intervention (this is a modified standard of care oral health intervention, which will include having plaque removed from your teeth, gums and oral mucosa using dental instruments and soft brushes). Cleansing of the oral mucosa will be performed by rinsing your mouth with an antibacterial solution.

Final Study Visit

The final study visit will occur approximately 3 months after the final chemoradiation treatment visit and all participants will have the option to receive a professional dental cleaning and fluoride treatment.

You will not be asked to interrupt your standard of care treatment for oral mucositis as recommended by your treating physician.

(See contact information on the reverse side to learn how to join the study.)