

# Testing the addition of the drug BMX-001, a radioprotector, or a placebo to the usual chemoradiation therapy for patients with head and neck cancer

**NRG**  
ONCOLOGY

*Advancing Research. Improving Lives.™*



Visit the patient  
webpage for this study:



## ABOUT THE TRIAL

NRG-CC013 is a clinical study that will test whether adding the drug BMX-001 to the usual cisplatin chemotherapy and radiation therapy reduces inflammation and mouth sores when compared to cisplatin chemotherapy and radiation therapy alone. Typically, people with head and neck cancer are treated with cisplatin chemotherapy and radiation therapy, which commonly cause the side effects of inflammation and mouth sores. There are no standard methods or medicines for the prevention of mouth and throat inflammation, mouth sores and ulceration, and mouth and throat pain from cisplatin and radiation for head and neck cancer. Management of these side effects typically consists of using mouth rinses and pain medications during treatment and for several weeks after completion of treatment. Researchers want to know if adding BMX-001 to the usual treatment is better or worse than the usual approach for your head and neck cancer.

## ABOUT NRG ONCOLOGY

As one of the five research groups in the National Cancer Institute's (NCI) National Clinical Trials Network (NCTN), NRG Oncology carries out clinical trials on gender-specific malignancies, including gynecologic, breast, and prostate cancers, and on localized or locally advanced cancers of all types. NRG Oncology's extensive research organization includes investigators, medical oncologists, radiation oncologists, surgeons, physicists, pathologists, and statisticians. The NRG Oncology includes more than 1,300 research sites worldwide, primarily in the United States and Canada. NRG Oncology is a non-profit research organization, funded mainly through grants from the NCI. To contact NRG Oncology, call 267-519-6630 or email [info@nrgoncology.org](mailto:info@nrgoncology.org)

# Frequently Asked Questions

## **What is a clinical trial?**

Clinical trials are research studies that look to find better ways to prevent, diagnose, or treat disease.

## **Who can join this study?**

People with head and neck cancer that will be receiving the usual treatment of cisplatin chemotherapy and radiation therapy.

## **Am I required to be in this study?**

No. Taking part in this study is voluntary. You are free to choose to participate or not to participate. If you choose to participate in this study, you are able to leave the study at any time. If you decide not to take part in this study, your doctor will discuss other treatment options with you.

## **What are the possible treatments?**

If you decide to take part in this study, you will either get the study drug BMX-001 or a placebo for up to 8 weeks during cisplatin and radiation therapy. You will also be asked to complete surveys 11 times during the study. You will continue to receive the usual symptom management for pain, swallowing discomfort, and side effect management.

## **How long will I be in this study?**

After you finish your study treatment, your doctor will continue to follow your symptoms for 2 years and watch you for side effects. They will check you when you finish treatment at 1, 3, 6, 12 and 24 months after treatment. This means you will keep seeing your doctor for 2 years after treatment.

## **Are there side effects?**

There may be some. The drug used in this study may cause a reaction after injection that includes itching, flushing, irritation, swelling, hives, temporary changes in skin color, and/or decreased heart rate. There is also a risk that you could have other side effects from the study drug, cisplatin, or radiation. Your doctor will review all of the potential side effects with you.

## **MORE INFORMATION**

Visit the National Cancer Institute website at <https://www.cancer.gov> for more information about studies or general information about cancer.

You may also call: 1-(800)-4-CANCER (1-800-422-6237).