Can gene risk based on the Decipher risk score inform hormonal therapy treatment with radiation for unfavorable intermediate risk prostate cancer?

NRG ONCOLOGY

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Visit the patient webpage for this study:

ABOUT THE TRIAL

NRG-GU010 is a clinical study for men with unfavorable intermediate risk prostate cancer that provides treatment options based on gene risk score. The prostate tumor tissue from your biopsy will be tested for different genes that all together predict the risk of your cancer spreading. This is called the Decipher risk score.

If you have a low gene risk score, you will be assigned to the part of the study that compares radiation therapy alone to the usual combination of radiation and hormone therapy. If you have a higher gene risk score, you will be assigned to the part of the study that compares adding the study drug darolutamide to the usual combination of radiation and hormone therapy.

Researchers are performing this study to see if radiation alone is as effective at controlling cancer for men with a low gene risk score. Additionally, researchers want to know if adding another new hormone therapy drug to the usual combination of radiation and hormone therapy increases the length of time without prostate cancer spreading for men with a higher gene risk score.

VERSION DATE: 2/24/2025

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 sex-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

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?

Men who are 18 years or older who have localized prostate cancer that is "unfavorable intermediate risk" based on your physician's evaluation and risk factors such as PSA, Gleason score, and tumor stage.

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 the study, you will be assigned to one of four possible study groups.

<u>If you have low Decipher risk score, you will get either:</u>
The usual radiation therapy for 2-11 weeks depending on type of radiation therapy given by your doctor with OR without the usual hormone drugs for up to 6 months.

<u>If you have a higher Decipher risk score you will get either:</u>
The usual hormone drugs for up to 6 months plus the usual radiation therapy for 2-11 weeks depending on the type of radiation therapy given by your doctor, or

The usual hormone drugs for up to 6 months, the usual radiation therapy, and the study drug, darolutamide, for 6 months. Darolutamide is approved by the FDA for use in prostate cancer that does not respond to usual hormone therapy but is not yet approved for your type of prostate cancer. Radiation therapy may last 2-11 weeks, depending on the type of radiation therapy given by your doctor.

How long will I be in this study?

If you are in the group receiving radiation therapy alone your treatment can last up to 11 weeks depending on the type of radiation therapy you receive. The other three groups receiving radiation plus hormone therapy will receive treatment for six months.

After you finish your study treatment, your doctor will continue to follow your condition and watch for side effects and cancer control.

Are there side effects?

There may be some. The most common side effects of the study drug darolutamide include: tiredness, rash, pain in arms or legs, or decrease in white blood cell counts. The most common radiation-related side effects include: tiredness and changes in urinary, bowel, or sexual function. Some of the most common hormone suppression drug-related side-effects include hot flashes, tiredness, elevated blood liver enzymes, skin rash, pain, or decreased sexual function or sexual desire. Your doctor will review all potential side effects with you.

MORE INFORMATION

Visit the National Cancer Institute website at <u>https://www.cancer.gov</u> for more information about studies or general information about cancer.
You may also call: 1-(800)-4-CANCER (1-800-422-6237).