NRG Oncology Clinical Trial: NRG-GU007

Randomized Phase II Trial of Niraparib with Standard Combination Radiotherapy and Androgen Deprivation Therapy (ADT) in High Risk Prostate Cancer (With Initial Phase I)

About the trial

NRG-GU007 is a clinical trial studying a new anti-cancer drug called niraparib and its effects on patients with prostate cancer who have a high chance of that cancer coming back. Typically, patients who have this type of prostate cancer are treated with a combination of hormone and radiotherapy. NRG-GU007 will take place in two phases. In Phase I, doctors will be determining the safety of adding the study drug niraparib to the usual treatment by following patients for any side effects that may occur. If niraparib is deemed safe, Phase II of this study will then compare the usual treatment of hormone and radiotherapy to the usual treatment with the addition of niraparib to see if the study drug combination is as good as, better, or worse than the typical approach to your 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 215-854-0716 or email info@nrgoncology.org.
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 with prostate cancer that has a high chance of returning.

Can I change my mind if I choose to take part in this study?
Yes. Taking part in this study is voluntary. 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 study treatments?
In the first phase of this study, participants will receive the usual hormonal drugs for up to 24 months in addition to the usual radiation therapy for 6 to 9 weeks and the experimental study drug, niraparib, for up to 12 months. In the second phase of this study, participants will be randomly assigned to one of two possible treatment groups. Treatment Group 1 will receive the usual hormonal drugs for up to 24 months plus the usual radiotherapy for 6 to 9 weeks. Treatment Group 2 will receive the usual hormonal drugs for up to 24 months, the usual radiotherapy for 6 to 9 weeks, plus the experimental drug, niraparib, for up to 12 months.

How long will I be in this study?
In both the first and second phases of this study, participants will receive treatment for up to 24 months. Your doctor will follow you for side effects every 6 months for 3 years after treatment, then once a year for the next 3 years.

Are there side effects?
There may be. Some of the most common side effects of hormone suppression therapy include hot flashes, changes in sexual desire or function, tiredness, breast tenderness or enlargement, or loss of bone tissue. Some of the most common side effects of radiation to the prostate bed include a more frequent need or urgency with urination, slower urinary flow, hair loss at treatment area, tiredness, or abnormal sexual function. Some of the most common side effects of niraparib are anemia, bruising, constipation or changes in bowels, nausea, decreased appetite, pain, difficulty sleeping, headache, tiredness, infection, shortness of breath, high blood pressure, cough, dizziness, and abnormal heart beat. There may be some side effects of niraparib when given together with radiation that the study doctors do not yet know about. Your doctor may 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)