NRG Oncology Clinical Trial: NRG-GU008

Randomized Phase III Trial Incorporating Abiraterone Acetate with Prednisone and Apalutamide and Advanced Imaging into Salvage Treatment for Patients with Node-Positive Prostate Cancer after Radical Prostatectomy
NCT04134260

About the trial
NRG-GU008 is a clinical study that is comparing the use of standard treatment for node-positive prostate cancer after prostatectomy, which is hormone therapy and radiation therapy, to the use of apalutamide and abiraterone acetate with prednisone added to the usual treatment. The addition of apalutamide and abiraterone acetate with prednisone to the usual treatment could stabilize your cancer and prevent it from spreading. This study will help doctors learn if this different approach is better, the same, or worse than the usual approach. To decide if it is better, the study doctors will be looking to see if the study approach increases the time without prostate cancer spreading compared to the usual approach. The study drugs, apalutamide and abiraterone acetate with prednisone, are already approved by the FDA for use in prostate cancer. However, most of the time abiraterone acetate with prednisone is not used until hormone drugs stop working and apalutamide is not used until hormone drugs stop working and after prostate cancer has spread.

Does adding two new drugs to usual therapy after radical prostatectomy delay the spread of prostate 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.
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 18 years of age and older who have pathologically node-positive prostate cancer with nodal involvement only in the pelvis in the prostatectomy biospecimen. There are other detailed eligibility requirements that doctors will discuss with you.

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?
If you decide to take part in this study, you will get either: the usual hormone drugs, given by injection, for up to 24 months plus the usual radiation therapy for 7-8 weeks, or, you will get the usual hormone drugs for up to 24 months, the usual radiation therapy for 7-8 weeks, plus the study drugs, apalutamide and abiraterone acetate, taken by mouth, for 24 months. Abiraterone acetate must be taken with a steroid called prednisone.

How long will I be in this study?
The treatment arm of the study lasts up to 24 months. After you finish your study treatment your doctor will continue to follow your condition and watch you for side effects. The doctor will check you every 6 months for 3 years after treatment, and then annually for your lifetime.

Are there side effects?
There may be. Some of the known side effects are: tiredness; rash; itching; pain; weight loss; swelling; high blood pressure; fall; broken bone; hot flashes; diarrhea. There may be some risks that the study doctors do not yet know about. 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).