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Summary of Research Results for RTOG-1115: Phase III Trial of Dose Escalated Radiation Therapy and Standard Androgen Deprivation Therapy (ADT) with a GnRH Agonist vs. Dose Escalated Radiation Therapy and Enhanced ADT with a GnRH Agonist and TAK-700 for Men with High Risk Prostate Cancer

Introduction

This summary reviews the main results of the study. There may be benefits and risks to learning study results. A benefit for some people is knowing that they contributed to the research and their participation is appreciated. Another benefit is what was learned from the study may help them make decisions about their health care now or in the future.

For some people, a risk is getting results that make them feel distressed or remember a difficult time in their lives. Some people may feel upset about the study results if the study did not help their condition.

Please talk with your doctor about any questions you may have about this summary. Your doctor can help explain these results to you in relation to your medical concerns.

NRG Oncology thanks you for your participation in this research. Your participation has helped us learn about and advance cancer care.

Background of the study

This study evaluated the addition of orteronel, a CYP17A1 inhibitor, to radiation therapy (RT) plus androgen deprivation therapy (ADT) in men with high-risk prostate cancer. The study evaluated the overall survival (OS) for an accrual goal of 900 men with high-risk prostate. Enrollment for the study was halted early due to discontinuation of orteronel development by the manufacturer and the trial redesigned to focus on multiple measures of disease progression to metastasis or death.

What did the study involve?

After enrolling on this study, participants were randomized to standard therapy (RT plus 2 years of ADT) or standard therapy plus 2 years of orteronel.

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What were the major findings of the study?

The addition of orteronel to RT and ADT did not result in significant improvement in any efficacy outcomes, although information was limited by poor drug tolerance and early termination of accrual thus limiting statistical power. Encouragingly, orteronel did not worsen the Health-Related Quality of Life (HRQOL) impacts of RT and ADT.

Are there any steps that may need to be taken at this time or in the future for those who participated in the study?

For participants in this study, there are no immediate or long-term steps that need to be considered because of these findings. All participants in this study have completed their treatment and should be followed by their doctor.

What did the researchers learn that will be helpful to other people with this condition?

Based on the study results, there is not much we can recommend. However, intensification of ADT with better tolerated agents remains an appealing strategy for the treatment of high-risk localized prostate cancer.

Who can I contact for further information?

Please talk with your doctor about any questions or concerns you may have about this summary. Further details about the design, conduct and results of this study are available at www.clinicaltrials.gov. Once you access the webpage, you can search by NRG Oncology study number.

List of publications with references that were generated from this study.

1. Hamstra DA, Dignam JJ, Bruner DW, Michaelson MD, Bachand F, Master V, Torres MA, Saylor PJ, Wallace RE, Vapiwala N, Efstathiou JA, Roach M 3rd, Rosenthal SA, Raben A, Morgan SC, Kavadi VS, Spratt DE, Michalski JM, Seiferheld W, Pugh SL, Movsas B, Sandler H. Phase III trial of dose escalated radiation therapy and standard androgen deprivation therapy (ADT) vs. dose escalated radiation therapy and enhanced ADT with orteronel for men with high-risk prostate cancer (NRG/RTOG 1115). Int J Radiat Oncol Biol Phys. 2025 Jul 23:S0360-3016(25)06022-5. doi: 10.1016/j.ijrobp.2025.07.1425. Epub ahead of print. PMID: 40712984.