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Summary of Research Results for NRG/RTOG-1112: Randomized Phase III Study Of Sorafenib Versus Stereotactic Body Radiation Therapy Followed By Sorafenib In Hepatocellular Carcinoma

Introduction

First and foremost, thank you for participating in this study. Your energy, effort, and willingness have the potential to help many people. Without assistance from individuals like you, making advances would be nearly impossible. 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 more about your disease as described below.

Background of the study

Liver cancer (called hepatocellular carcinoma or HCC) is one of the most common types of cancer. For patients with this disease and cannot have surgery or have local treatments, the usual treatment option has been the oral drug sorafenib. Stereotactic body radiation therapy (SBRT), which is the use of focused high dose radiation has also been used to treat this disease.

The purpose of this study was to determine if the addition of stereotactic body radiation therapy (SBRT) to sorafenib can help patients better compared to patients taking sorafenib alone.

What did the study involve?

After enrolling in this study, participants were randomized to receive sorafenib or SBRT followed by sorafenib.

What were the major findings of the study?

One hundred and seventy-seven patients participated in the study because enrollment ended earlier than planned due to the change in the standard treatment approach during the trial. Although the enrollment ended earlier than planned, the study showed that patients who received stereotactic body radiation therapy lived longer compared to patients who had only received sorafenib.

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, it was found that in patients with locally advanced liver cancer, SBRT was associated with patients living longer compared to sorafenib alone. Due to this, SBRT should be recommended as part of the usual treatment option for selected liver cancer patients.

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. Dawson LA, Winter KA, Knox JJ, Zhu AX, Krishnan S, Guha C, Kachnic LA, Gillin MT, Hong TS, Craig TD, Williams TM, Hosni A, Chen E, Noonan AM, Koay EJ, Sinha R, Lock MI, Ohri N, Dorth JA, Delouya G, Swaminath A, Moughan J, Crane CH. Stereotactic Body Radiotherapy vs Sorafenib Alone in Hepatocellular Carcinoma: The NRG Oncology/RTOG 1112 Phase 3 Randomized Clinical Trial. JAMA Oncol. 2025 Feb 1;11(2):136-144. doi: 10.1001/jamaoncol.2024.5403. Erratum in: JAMA Oncol. 2025 Apr 10. doi: 10.1001/jamaoncol.2025.0928. PMID: 39699905; PMCID: PMC11843352.