NRG ONCOLOGY

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Summary of Research Results for NRG/RTOG 1119: Phase II Randomized Study Of Whole Brain Radiotherapy/Stereotactic Radiosurgery In Combination With Concurrent Lapatinib In Patients With Brain Metastasis From HER2-Positive Breast Cancer- A COLLABORATIVE STUDY OF NRG Oncology AND KROG

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

The purpose of this study was to evaluate the effects of adding lapatinib to standard brain radiation therapy for patients with brain metastasis from HER2-positive breast cancer. The study aimed to find out whether radiation therapy alone or lapatinib plus radiation therapy is better at safely improving tumor control. In this study, patients received either lapatinib plus radiation therapy or radiation therapy alone. About 143 people took part in this study.

What did the study involve?

After enrolling on this study, participants were randomized to one of two study groups, treatment Arm A and Arm B. Both groups received the type of radiation therapy most appropriate for them, either whole brain radiation therapy (WBRT) or stereotactic radiosurgery (SRS). Patients randomized to Arm A received radiation therapy only, while Arm B patients received radiation therapy in addition to daily oral lapatinib for 6 weeks, starting on the first day of

radiation.

What were the major findings of the study?

One hundred forty-three (143) patients were randomized on NRG/RTOG 1119 from 43 institutions in the United States, Canada, and South Korea and assessed for eligibility. Seven patients did not meet inclusion criteria, leaving 136 patients.

Adding 6 weeks lapatinib to radiation therapy did not improve the number of patients whose tumors got smaller or disappeared at 12 weeks. Adding lapatinib to radiation therapy showed improvement of 4-week objective response rate, suggesting a short-term benefit from concomitant therapy.

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?

Clinicians can use this data to identify patients who might benefit most from combination therapies. The study findings encourage future research into targeted radiation strategies with CNS-active HER2 inhibitors, or drugs that can reach and work in the brain..

Patients can be better informed about treatment options and ask about clinical trials involving medicines that help radiation work better (radiosensitizers) or newer HER2-targeted drugs.

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.

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

1. Kim IA, Winter KA, Sperduto PW, et al. Concurrent Lapatinib With Brain Radiation Therapy in Patients With HER2+ Breast Cancer With Brain Metastases: NRG Oncology-KROG/RTOG 1119 Phase 2 Randomized Trial. *Int J Radiat Oncol Biol Phys*. 2024;118(5):1391-1401. doi:10.1016/j.ijrobp.2023.07.019