NRG ONCOLOGY

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Summary of Research Results for NRG/RTOG 0631: Phase II/III Study of Image-Guided Radiosurgery/SBRT for Localized Spine Metastasis

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

The study assessed whether radiosurgery can be used to treat pain caused by cancer that has spread to the spine. Radiosurgery is a high-technology radiation treatment method that uses highly focused x-rays to deliver one high-dose of radiation to a specific area of the body. Patients who do not receive radiosurgery may receive standard radiation therapy, which is given over one or several lower-dose treatment sessions compared to a single high-dose treatment.

The first part of this study tested whether radiosurgery can be used to treat cancer that has spread to the spine and is causing pain. The second part of this study tested whether radiosurgery improves pain response compared with standard radiation therapy.

What did the study involve?

Participants enrolled on the first part of the study received one high-dose radiosurgery treatment to their spine. Participants enrolled on the second part of the study were randomized to one of two groups: one group received standard radiation therapy and the other group received one radiosurgery to their spine, as was done in the first part of the study. Participants were followed by their study doctor for pain and treatment response.

What were the major findings of the study?

The first part of the study showed that radiosurgery can successfully be used to manage pain in patients with cancer that has spread to the spine. In the second part of the study, 339 patients were randomized to radiosurgery or standard radiation therapy. Compared with standard radiation therapy, radiosurgery was not found to be better at improving patient-reported pain 3 months after treatment. At 24 months after treatment, there were no differences in spinal cord complications for patients treated with radiosurgery compared to standard radiation 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?

Based on the study results, patients can discuss with their doctors the use of either radiosurgery or standard radiation therapy for pain due to cancer that has spread to the spine. Either treatment can be used safely, given in a single dose and are equally effective in controlling pain.

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. Ryu S, Deshmukh S, Timmerman RD, et al. Stereotactic Radiosurgery vs Conventional Radiotherapy for Localized Vertebral Metastases of the Spine: Phase 3 Results of NRG Oncology/RTOG 0631 Randomized Clinical Trial. JAMA Oncol. 2023 Jun 1;9(6):800-807. doi: 10.1001/jamaoncol.2023.0356. PMID: 37079324; PMCID: PMC10119775.