

Summary of Research Results for NRG-BN002: Testing the Addition of Ipilimumab, Nivolumab, or Both to Usual Drug Therapy for Newly Diagnosed Glioblastoma Brain Tumors

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

This study looked at whether two additional drugs—ipilimumab and nivolumab—are safe to use with the usual drug, temozolomide, in patients with newly diagnosed glioblastoma brain tumors. These drugs have been used safely in treating other cancers, but they had not been tested with temozolomide in patients with newly diagnosed glioblastoma.

What did the study involve?

Before entering the study, all patients received radiation therapy and temozolomide. After that, patients were placed into two groups. One group received temozolomide plus ipilimumab, and the second group received temozolomide plus nivolumab. Once both combinations were found to be safe, a third group of patients received temozolomide plus both ipilimumab and nivolumab.



What were the major findings of the study?

Thirty-two patients were enrolled from 9 institutions through the NRG Oncology network. Six patients received temozolomide plus ipilimumab, 6 patients received temozolomide plus nivolumab, and 20 patients received temozolomide plus both drugs.

Ipilimumab and nivolumab were found to be safe to use with temozolomide in patients with newly diagnosed glioblastoma. Their side effects were similar to those seen in patients with other cancers, and using both drugs together did not cause more side effects than using each one alone

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, the researchers will be exploring a larger trial for newly diagnosed glioblastoma patients to see if the drug combinations work better than the usual treatment, specifically to determine improvement in either survival or prolongation of the period of time before the disease progresses.

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. Sloan AE, Winter K, Gilbert MR, et al. NRG-BN002: Phase I study of ipilimumab, nivolumab, and the combination in patients with newly diagnosed glioblastoma. *Neuro Oncol.* 2024 Sep 5;26(9):1628-1637. doi: 10.1093/neuonc/noae058. PMID: 38874333; PMCID: PMC11376446.