

Summary of Research Results for GOG-0264: A Randomized Phase II Trial of Paclitaxel and Carboplatin vs. Bleomycin, Etoposide, and Cisplatin for Newly Diagnosed Advanced Stage and Recurrent Chemonaive Sex Cord-Stromal Tumors of the Ovary

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

For a type of ovarian cancer known as a stromal tumor, the standard treatment has been chemotherapy with bleomycin, etoposide, and cisplatin. This study tested whether a newer, more well-tolerated chemotherapy combination, paclitaxel and carboplatin, works no worse (or better) at controlling this type of cancer, while potentially causing fewer side effects.

What did the study involve?

Participants were randomly assigned to one of two groups: one group received paclitaxel and carboplatin once every 3 weeks, for 6 cycles; and the other group received bleomycin, etoposide, and cisplatin once every 3 weeks, for 4 cycles. The study looked at the length of time a participant lives without their cancer progressing or getting worse.

What were the major findings of the study?

This study enrolled 63 participants in the United States between 2010 to 2020. The study closed in June 2020 because early results showed that the study was not going to be able to prove that paclitaxel and carboplatin was no worse than bleomycin, etoposide, and cisplatin in terms of living without cancer progression. Results also showed that participants who received paclitaxel and carboplatin had less serious side effects than those who received bleomycin, etoposide, and cisplatin.

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, paclitaxel and carboplatin did not improve outcomes as compared to bleomycin, etoposide, and cisplatin. However, doctors may still consider either chemotherapy regimens for patients whose ovarian cancer is advanced or has come back, depending on factors like side effects, overall health, and treatment goals.

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. Brown J, Miller A, Holman LL, Backes F, Nagel C, Bender D, Miller DS, Powell MA, Westin SN, Bonebrake A, Muller CY, Secord AA, Crane E, Schorge J, Tew WP, Sood AK, Bookman MA, Aghajanian C, Gershenson DM. Results of a randomized phase II trial of paclitaxel and carboplatin versus bleomycin, etoposide and cisplatin for newly diagnosed and recurrent Chemo-naïve stromal ovarian tumors: An NRG oncology/gynecologic oncology group study14. *Gynecol Oncol*. 2024 Nov;190:283-290. doi: 10.1016/j.ygyno.2024.09.002. Epub 2024 Sep 12. PMID: 39265466.

