

Summary of Research Results for GOG-0279: Testing the Combination of Cisplatin, Gemcitabine, and Radiation Therapy to Treat Patients With Cancer of the Vulva That Can Not Be Surgically Removed

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 purpose of the study was to find out if radiation therapy plus the addition of the drugs cisplatin and gemcitabine works to treat patients with cancer of the vulva that is not able to be surgically removed. To determine how well radiation therapy, cisplatin, and gemcitabine worked, the investigators looked at whether or not the cancer completely resolved on the vulva and whether or not it came back on the vulva or somewhere else.

What did the study involve?

After enrolling on this study, participants' inguinal (groinal) lymph nodes were either surgically removed if surgery was possible or biopsied if surgery was not possible. Participants then received weekly treatment with cisplatin and gemcitabine plus daily radiation (5 days per week) for 5-7 weeks. After finishing the drug and radiation treatment, participants either had a biopsy

of the vulva if no cancer remained or surgery to remove cancer on the vulva or groin if cancer was still present.

What were the major findings of the study?

Fifty-seven patients enrolled on the study and 52 patients were included in the researchers' analysis. Of 52 patients who had vulvar biopsies or surgery after radiation and drug treatment, 38 (73%) were found to have no more cancer. After 1 year, 74% of patients were still cancer free.

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 concluded that weekly treatment with cisplatin and gemcitabine along with daily radiation helps prevent cancer coming back in patients with vulvar cancer that can not be surgically removed.

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. Horowitz NS, Deng W, Peterson I, Mannel RS, Thompson S, Lokich E, Myers T, Hanjani P, O'Malley DM, Chung KY, Miller DS, Ueland FR, Dizon DS, Miller A, Mayadev JS, Leath CA 3rd, Monk BJ. Phase II Trial of Cisplatin, Gemcitabine, and Intensity-Modulated Radiation Therapy for Locally Advanced Vulvar Squamous Cell Carcinoma: NRG Oncology/GOG Study 279. *J Clin Oncol*. 2024 Jun 1;42(16):1914-1921. doi: 10.1200/JCO.23.02235. Epub 2024 Apr 4. PMID: 38574312; PMCID: PMC11585925

