"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"

Protocol

GOG 0264

Purpose

The purpose of this study is to find out whether treatment with the drugs paclitaxel and carboplatin works better to control this type of cancer than treatment with the drugs bleomycin, etoposide and cisplatin, which is the standard treatment for this type of cancer. Another purpose of this study is to find out what side effects are caused by treatment with these drug combinations. Another purpose of this study is to examine whether inhibin levels (a blood test) might be a good way to know how someone is responding to treatment. In this study subjects will get paclitaxel and carboplatin (considered the experimental therapy) **or** bleomycin, etoposide and cisplatin (considered the standard therapy).

Investigator

Dr. Abbie Fields

Eligibility

To be eligible for this study, patients must meet several criteria**, including but not limited** to the following:

- ≥ 18 year old females.
- Patients diagnosed with histologically confirmed ovarian stromal tumor [granulosa cell tumor, granulosa cell–theca cell tumor, Sertoli-Leydig cell tumor (androblastoma), steroid (lipid) cell tumor, gynandroblastoma, unclassified sex cord-stromal tumor, sex cord tumor with annular tubules].
- Patients must have newly diagnosed, Stage IIA – IV disease and must be entered within eight weeks from surgery; they may have either measurable residual disease by RECIST criteria, or they may have no measurable residual disease; OR, they must have biopsy-proven recurrent disease of any stage and have never received cytotoxic chemotherapy.
- Patients must have a GOG performance Grade of 0, 1, or 2.
- Patients in the measureable disease cohort must have at least one "target lesion" to be used to assess response on this protocol as defined by RECIST 1.1 (Section 8.0). Tumors within a previously irradiated field will be designated as "non-target" lesions unless progression is documented or a biopsy is obtained to confirm persistence at least 90 days following completion of radiation therapy.

Ineligibility

- Patients who have received any prior cytotoxic chemotherapy or biologics for sex cord-stromal tumors (SCSTs).

- Patients with apparent Stage I disease who have not undergone a staging procedure.
- Patients with a history of other invasive malignancies, with the exception of non-melanoma skin cancer, are excluded if there is any evidence of other malignancy being present within the last five years.

For more information about this study and to inquire about eligibility, please contact the Research Staff at 410-601-6120.

Locations

Sinai Hospital of Baltimore
Northwest Hospital Center

ClinicalTrials.gov
Visit **ClinicalTrials.gov** for full clinical trial description