

A Randomized Phase III, Two-Arm Trial of Paclitaxel/Carboplatin/Maintenance Letrozole Versus Letrozole Monotherapy in Patients with Stage II-IV, Primary Low-Grade Serous Carcinoma of the Ovary or Peritoneum

Status: Recruiting

Eligibility Criteria

Sex: Female

Age Group: 18 years and over

This study is NOT accepting healthy volunteers

Inclusion Criteria:

- newly diagnosed, stage II-IV low-grade serous ovarian cancer: Ovarian cancer includes ovarian, fallopian tube and primary peritoneal cancers - must have undergone an attempt at maximal cytoreductive surgery and a bilateral salpingo-oophorectomy - ambulatory and capable of all selfcare but unable to carry out any work activities; up and about more than 50% of waking hours - surgery no more than eight weeks before starting the study - able to take medications by mouth - contact study staff for additional inclusion criteria

Exclusion Criteria:

- have received neoadjuvant or adjuvant chemotherapy or radiotherapy for the treatment of this disease - received previous hormone therapy for the treatment of this disease - history of severe cardiac disease - central nervous system metastases - active (except for uncomplicated urinary tract infection) or uncontrolled systemic infection - neuropathy causing more than moderate pain and affecting daily activity

Conditions & Interventions

Conditions:

Cancer, Women's Health

Keywords:

Fallopian Tube Serous Cancer, Ovarian Low Grade Serous Cancer, Peritoneal Serous Cancer, Clinics and Surgery Center (CSC)

More Information

Description: The purpose of this study is to compare the treatment of carboplatin/paclitaxel and letrozole hormonal therapy to letrozole alone. Letrozole is a drug called an aromatase inhibitor, which indirectly stops the body from producing estrogen. The use of the hormonal therapy drug, letrozole without chemotherapy may shrink or stabilize your cancer in the same way that chemotherapy also does, but without the added side effects of chemotherapy. Half of women in this study will receive letrozole with paclitaxel/carboplatin and the other half will receive letrozole alone.

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