

**GOG 0258: A Randomized Phase III Trial of Cisplatin and Tumor Volume Directed Irradiation Followed by Carboplatin and Paclitaxel VS. Carboplatin and Palitaxel for Optimally Debulked, Advanced Endometrial Carcinoma**

***Fast Facts***

**No drugs provided.**

**Eligibility Criteria**

1. All patients with FIGO Surgical Stage III or IVA endometrial carcinoma, including clear cell and serous papillary and undifferentiated carcinomas.
2. Surgical Stage III disease includes those patients with positive adnexa, tumor invading the serosa, positive pelvic and/or para-aortic nodes, or vaginal involvement. Patients with positive pelvic washings as the only extra-uterine disease are eligible only if the histology is clear cell or serous papillary.
3. Surgical Stage IVA includes patients with bladder or bowel mucosal involvement, but no spread outside the pelvis.
4. Surgery must have included a hysterectomy and bilateral salpingo-oophorectomy. Pelvic lymph node sampling and para-aortic lymph node sampling are optional.
5. Patients with a GOG Performance Status of 0, 1, or 2.
6. Patients with adequate organ function, reflected by the following parameters:
  - a. WBC  $\geq$  3000/mcl
  - b. Absolute neutrophil count (ANC)  $\geq$  1,500/mcl
  - c. Platelet count  $\geq$  100,000/mcl
  - d. SGOT, SGPT, and alkaline phosphatase  $\leq$  2.5 X normal.
  - e. Bilirubin  $\leq$  1.5 X normal
  - f. Creatinine  $\leq$  1.6 mg/dl
7. Patients who have met the pre-entry requirements specified in Section 7.0; testing values/results must meet eligibility criteria specified in Section 3.1.
8. Patients who have signed an approved informed consent and authorization permitting release of personal health information.
9. Patients must be 18 years of age or older.

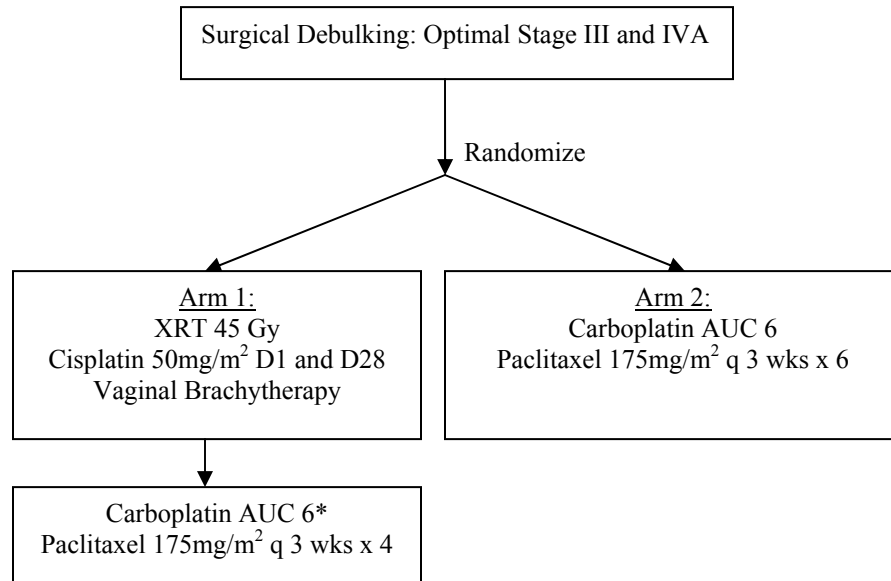
**Ineligibility Criteria**

1. Patients with carcinosarcoma.
2. Patients with recurrent endometrial cancer.
3. Patients with residual tumor after surgery (any single site) exceeding 2 cm in maximum dimension.
4. Patients who have had pelvic or abdominal radiation therapy.
5. Patients with positive pelvic washings as the only extra-uterine disease are NOT eligible if the histology is other than **clear cell or papillary serous carcinoma**.
6. Patients with a history of other invasive malignancies, with the exception of non-melanoma skin cancer, are excluded if there is any evidence of active malignancy within the last five years. Patients are also excluded if their previous cancer treatment contraindicates this protocol therapy.
7. Patients with a history of serious co-morbid illness or uncontrolled illnesses that would preclude protocol therapy.
8. Patients with an estimated survival of less than three months.
9. Patients with Stage IVB endometrial cancer.
10. Patients with parenchymal liver metastases.
11. Patients who have received prior chemotherapy for endometrial cancer.
12. Patients with a history of myocardial infarction, unstable angina, or uncontrolled arrhythmia within 3 months from enrollment.

**Pre-Study Parameters**

1. History and physical including toxicity assessment, pelvic examination
2. Labs including, Hgb or Hct, ANC, Differential, Platelets Creatinine, Bilirubin, SGOT, SGPT, Alk Phos,
3. Scans including Chest x-ray, CT abdomen and pelvis, CT chest (required is CXR is abnormal)

**Treatment**



\* First dose of Carboplatin will be at AUC of 5.  
 In subsequent cycles, the dose will be escalated  
 as described in section 6.2 G-CSF use is  
 required with carbo/taxol.

No drugs provided.