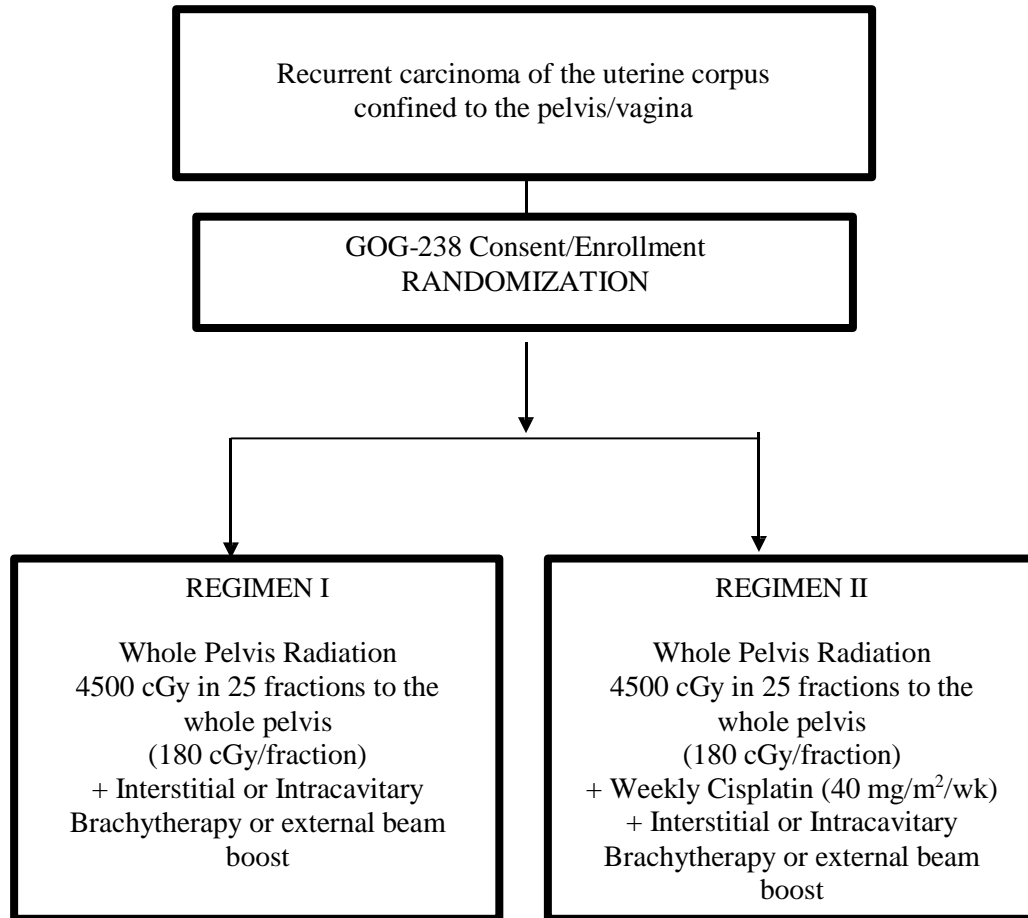


SCHEMA

Institutional IMRT Credentialing is required before registering any patient on this trial.
Knowledge Assessment must be completed by the treating radiation oncologist.



Patients with tumors involving the distal vagina with clinically negative groins, the bilateral inguino-femoral lymph node regions should be treated to 4500 cGy.

3-D conformal or IMRT boost is allowed for patients who are not candidates for brachytherapy.

3.0 PATIENT ELIGIBILITY AND EXCLUSIONS

3.1 Eligible Patients

- 3.11 All patients must have undergone complete hysterectomy and bilateral salpingo-oophorectomy at the time of the original therapy for their uterine carcinoma.
- 3.12 Patients must have a biopsy with histologically confirmed diagnosis of recurrent endometrial cancer confined to the pelvis and/or vagina and no evidence of extrapelvic disease.
- 3.13 Patients must have endometrial carcinoma including endometrioid adenocarcinoma, adenocarcinoma with squamous differentiation, mucinous adenocarcinoma, squamous cell carcinoma, mixed carcinoma, undifferentiated carcinoma, clear cell adenocarcinoma, and serous adenocarcinoma histologies.
- 3.14 Patients must have no evidence of extrapelvic disease. Complete workup staging should be performed prior to initiation of therapy to rule-out presence of metastatic disease. This should include: CT scan of the thorax with IV contrast, as well as a CT of the pelvis and abdomen with IV and PO contrast performed using multi-detector CT and equal or less than 5 mm slice thickness. If the patient is unable to tolerate contrast, then MRI with IV gadolinium should be performed. A chest x-ray should be done first, and if abnormal, then a CT scan of the chest should be done.
(10/8/08)
- 3.15 Primary surgical debulking before protocol therapy is permissible. This would include removal of gross symptomatic disease in the pelvis and/or vagina.
- Exenterative surgery is not permissible. Patients enrolled subsequent to revision 11 with complete resection of gross recurrent disease are eligible.
(05/14/2012)
- 3.16 Patients may have received prior hormone therapy and/or systemic chemotherapy. Such therapy must have been completed at least 6 months prior to study entry and the patient has clear evidence of disease subsequent to such therapy. Patients must not have received neoadjuvant chemotherapy for the present recurrent disease.
- 3.17 Patients must have GOG performance status 0, 1, or 2.
- 3.18 Patients must have an estimated survival greater than or equal to 3 months

- 3.19 Patients must have adequate:
 - 3.191 Bone Marrow Function: Absolute neutrophil count (ANC) \geq 1,500/mm³, equivalent to Common Toxicity Criteria (CTCAE v 3.0) grade 1. Platelets \geq 100,000/mm³ (CTCAE v3.0 grade 0-1).
 - 3.192 Renal Function: Creatinine \leq institutional upper limit normal (ULN), CTCAE v 3.0 grade 0. **Note: If creatinine > ULN, creatinine clearance must be >50 mL/min.**
 - 3.193 Hepatic Function: Bilirubin \leq 1.5 x ULN (CTCAE v3.0 grade 1). SGOT and alkaline phosphatase \leq 2.5 x ULN (CTCAE v3.0 grade 0-1).
 - 3.194 Neurologic Function: Neuropathy (sensory and motor) \leq CTCAE v3.0 grade 1.
- 3.110 Patients with ureteral obstruction must undergo stent or nephrostomy tube placement prior to study entry.
- 3.111 Patients who have met the pre-entry requirements specified in Section 7.0.
- 3.112 Patients must have signed an approved informed consent and HIPAA authorization.
- 3.2 Ineligible Patients
 - 3.21 Patients with evidence of disease outside of the pelvis, including presence of positive periaortic or inguino-femoral nodes.
 - 3.22 Patients who have received previous vaginal, pelvic, or abdominal irradiation.
 - 3.23 Patients who received chemotherapy directed at the present recurrence.
 - 3.24 Patients with septicemia or severe infection.
 - 3.25 Patients who have circumstances that will not permit completion of this study or the required follow-up.
 - 3.26 Patients with renal abnormalities, such as pelvic kidney, horseshoe kidney, or renal transplantation, that would require modification of radiation fields.
 - 3.27 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. Patients are also excluded if their previous cancer treatment contraindicates this protocol therapy.

- 3.28 Patients enrolled prior to revision 11 who have undergone complete surgical resection of the recurrent tumor and have no evidence of residual disease evaluable clinically and by CT or MRI imaging, following resection. **(05/14/2012)**
- 3.29 Patients who have a significant history of cardiac disease, i.e., uncontrolled hypertension, unstable angina, congestive heart failure, or uncontrolled arrhythmias within 6 months of registration.
- 3.210 Patients with history of active collagen vascular disease.
- 3.211 Patients with GOG Performance Grade of 3 or 4.