Adjuvant Therapy in POLE-Mutated and p53-Wildtype/NSMP Early Stage Endometrial Cancer RAINBO BLUE & TAPER

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Patients must have had surgery consisting of hysterectomy and bilateral salpingo-oophorectomy. Lymph node dissection can be performed as per institutional standards. There must be no macroscopic residual disease after surgery. * Patients must have histologically confirmed Stage I to III endometrial carcinoma which can be endometrioid, serous, clear cell, un/dedifferentiated, carcinosarcoma or mixed. * Patients' Eastern Cooperative Group (ECOG) performance status must be 0, 1, or 2. * HIV-infected patients on effective anti-retroviral therapy with undetectable viral load within 6 months are eligible for this trial. * Patients' age must be ≥ 18 years. * Patient consent must be appropriately obtained in accordance with applicable local and regulatory requirements. * Patient is able (i.e. sufficiently fluent) and willing to complete the patient-reported outcomes (PRO) questionnaires in either English, French or a validated language * Patients must be accessible for treatment and follow-up. Patients enrolled on this trial must be treated and followed at the participating centre * Protocol treatment is to begin within 10 weeks of hysterectomy/bilateral salpingo-oophorectomy

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Exclusion Criteria:

* Prior Neoadjuvant chemotherapy for current endometrial cancer diagnosis. * Prior pelvic radiation. * Patients with a history of other malignancies, except: carcinoma in-situ without evidence of invasive disease when resected, adequately treated non-melanoma skin cancer, or other tumours curatively treated with no evidence of disease for ≥ 5 years. * Clinical evidence of distant metastasis as determined by pre-surgical or post-surgical imaging (CT scan of chest, abdomen and pelvis or whole-body PET-CT scan) * Patients with a documented positive surgical margin. * Patients with a documented positive peritoneal washings, if performed.

Conditions & Interventions

Interventions:
RADIATION: Vaginal brachytherapy, RADIATION: Adjuvant radiotherapy (EBRT +/- brachytherapy), OTHER: Observation
Conditions:
Endometrial Cancer

More Information

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