Tailoring Therapy in Post-surgical Patients With Low-risk Endometrial Cancer

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 (total abdominal, laparoscopic or robotic-assisted) and bilateral salpingo-oophorectomy. Lymph node dissection can be performed as per institutional standards (sentinel or full lymphadenectomy). 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 * Patients' age must be \>= 18 years * Patient consent must be appropriately obtained in accordance with applicable local and regulatory requirements. Each patient must sign a consent form prior to enrollment in the trial to document their willingness to participate. A similar process must be followed for sites outside of Canada as per their respective cooperative group's procedures * 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. The baseline assessment must be completed within required timelines, prior to enrollment. Inability (lack of comprehension in English or French, or other equivalent reason such as cognitive issues or lack of competency) to complete the questionnaires will not make the patient ineligible for the study. However, ability but unwillingness to complete the questionnaires will make the patient ineligible * Patients must be accessible for treatment and follow-up. Patients enrolled on this trial must be treated and followed at the participating centre. This implies there must be reasonable geographical limits placed on patients being considered for this trial. The patient's city of residence may be required to verify their geographical proximity. (Call the CCTG office (613-533-6430) if questions arise regarding the interpretation of this criterion.) Investigators must assure themselves the patients enrolled on this trial will be available for complete documentation of the treatment, adverse events, and follow-up * Patients must agree to return to their primary care facility for any adverse events which may occur through the course of the trial * Protocol treatment is to begin within 10 weeks of hysterectomy/bilateral salpingo-oophorectomy * SUB-STUDY A: Patients with endometrial carcinoma (endometrioid, serous, clear cell, un-/dedifferentiated, carcinosarcoma, mixed), must have one of the following combinations of International Federation of Gynecology and Obstetrics (FIGO) stage, grade, and lymphovascular invasion (LVI): * Cohort A1: * Stage IA (not confined to polyp), grade 3, pN0, with or without LVI (Pelvic lymph node surgical assessment (sentinel or full lymphadenectomy) is required for grade 3 or stage II. Para-aortic lymphadenectomy is not mandated.) * Stage IB, grade 1 or 2, pNx/N0, with or without LVI * Stage IB, grade 3, pN0, without substantial LVI (Pelvic lymph node surgical assessment (sentinel or full lymphadenectomy) is required for grade 3 or stage II. Para-aortic lymphadenectomy is not mandated.) * Stage II (microscopic), grade 1 or 2, pN0, without substantial LVI (Pelvic lymph node surgical assessment (sentinel or full lymphadenectomy) is required for grade 3 or stage II. Para-aortic lymphadenectomy is not mandated.) (Substantial LVI is defined as \>= 3 foci per College of American Pathologists' reporting guideline) * Cohort A2: * Stage IA (not confined to polyp), grade 3, pNx, with or without LVI * Stage IB, grade 3, pNx, with or without LVI * Stage IB, grade 3, pN0, with substantial LVI (Substantial LVI is defined as \>= 3 foci per College of American Pathologists' reporting guideline) * Stage II (microscopic), grade 1 or 2, pNx, with or without LVI * Stage II (microscopic), grade 1 or 2, pN0, with substantial LVIƒõ * Stage II (microscopic), grade 3, pNx/N0, with or without LVI * Stage II non-microscopic, any grade, pNx/N0, with or without LVI * Stage III, any grade, pNx/N0-2, with or without LVI * Substantial LVI is defined as .3 foci per College of American Pathologists¡¦ reporting guideline * SUB-STUDY A: Patients must have a molecular classification of POLE mutation. * Note: patients in Cohort A2 should have a known POLE pathogenic mutation prior to consenting * SUB-STUDY B: Patients with endometrial carcinoma (endometrioid only), must have one of the following combinations of FIGO stage, grade, and lymphovascular invasion (LVI): * Stage IA (not confined to polyp), grade 3, pN0, with or without LVI (Pelvic lymph node surgical assessment \[sentinel or full lymphadenectomy\] is required for grade 3 or stage II. Para-aortic lymphadenectomy is not mandated) (Substantial LVI is defined as \>= 3 foci per College of American Pathologists' reporting guideline) * Stage IB, grade 1 or 2, pNx/N0, with or without LVI * Stage IB, grade 3, pN0, without substantial LVI (Pelvic lymph node surgical assessment \[sentinel or full lymphadenectomy\] is required for grade 3 or stage II. Para-aortic lymphadenectomy is not mandated) (Substantial LVI is defined as \>= 3 foci per College of American Pathologists' reporting guideline) * Stage II (microscopic), grade 1 or 2, pN0*, without substantial LVI (Pelvic lymph node surgical assessment \[sentinel or full lymphadenectomy\] is required for grade 3 or stage II. Para-aortic lymphadenectomy is not mandated) (Substantial LVI is defined as \>= 3 foci per College of American Pathologists' reporting guideline) * SUB-STUDY B: Patients must have molecular classification of p53wt/NSMP (based on normal p53 IHC, and absence of pathogenic POLE mutation or MMR deficiency) * SUB-STUDY B: Estrogen receptor positive (\> 10% of the tumour with positive nuclear staining) on IHC

Exclusion Criteria:

* Prior neoadjuvant chemotherapy for current endometrial cancer diagnosis * Prior pelvic radiation * Patients with a history of other malignancies, except: adequately treated non-melanoma skin cancer, curatively treated in-situ cancer of the cervix, or other solid 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) * SUB-STUDY A: Isolated tumour cell(s) identified in lymph node(s) for patients in Cohort A1 * SUB-STUDY B: Abnormal p53 and/or mismatch repair deficiency on immunohistochemistry without pathogenic POLE mutation. * Abnormal p53 can also be determined by TP53 mutations found on DNA testing. * SUB-STUDY B: p53wt/NSMP endometrial carcinoma with a MELF (microcystic, elongated and fragmented) pattern of myoinvasion and/or substantial lymphovascular invasion * SUB-STUDY B: Stage IA (not confined to polyp), grade 3, pN0, with substantial LVI. Stage IB, grade 1 or 2, pNx/N0, with substantial LVI * SUB-STUDY B: Isolated tumour cell(s) identified in lymph node(s)

Conditions & Interventions

Interventions:

OTHER: Clinical Observation, PROCEDURE: Computed Tomography, RADIATION: External Beam Radiation Therapy, PROCEDURE: High-Dose-Rate Vaginal Brachytherapy, PROCEDURE: Magnetic Resonance Imaging, PROCEDURE: Positron Emission Tomography, OTHER: Questionnaire Administration, PROCEDURE: X-Ray Imaging

Conditions:

Stage I Uterine Corpus Endometrial Stromal Sarcoma AJCC v8, Stage II Uterine Corpus Endometrial Stromal Sarcoma AJCC v8, Stage III Uterine Corpus Endometrial Stromal Sarcoma AJCC v8

More Information

Contact(s): ctrrecruit@vcu.edu

Principal Investigator:

Phase: PHASE2

IRB

Number:

Number:
System ID: NCT06388018
