Leveraging Methylated DNA Markers (MDMs) in the Detection of Endometrial Cancer, Ovarian Cancer, and Cervical Cancer

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria for Cohort 1: Patients will be ≥45 years of age and meet one of the following criteria: * Abnormal uterine bleeding * Postmenopausal bleeding OR Patients ages 18

•44 years of age and meet these criteria * Abnormal uterine bleeding * One risk factor for endometrial cancer (BMI ≥30 or PCOS or Tamoxifen use) Exclusion Criteria for Cohort 1: * Prior hysterectomy * Current known pregnancy diagnosis * Any prior pelvic or vaginal radiotherapy * Any prior cancer (except basal cell skin cancer) within the past 5 years * Chemotherapy within the past 5 years * Current biopsy-proven cervical, vaginal, or vulvar cancer or lower genital tract dysplasia * Current biopsy-proven endometrial cancer or endometrial hyperplasia * Current biopsy-proven benign endometrial polyp * Endometrial biopsy/sampling within the preceding 1 month showing benign endometrium Inclusion Criteria for Cohort 2: Patients will be ≥18 years of age and meet at least one of the following criteria: * Presence of biopsy-proven EC (any histology, including uterine carcinosarcoma) and surgical intervention planned. Surgical intervention can include any of the following: hysterectomy, D\&C, hysteroscopic resection * Biopsy showing AEH or EIN with surgical intervention planned. Surgical intervention can include any of the following: hysterectomy, D\&C, hysteroscopic resection, etc) Exclusion Criteria for Cohort 2: * Undergoing surgical procedure for recurrent or metastatic EC * Received preoperative neoadjuvant chemotherapy or radiotherapy for current EC diagnosis * Prior hysterectomy * Current known pregnancy diagnosis * Prior or current biopsy-proven cervical cancer * Presence of concomitant biopsy-proven cervical dysplasia * Any prior pelvic or vaginal radiotherapy * Any prior cancer (except basal cell skin cancer) within the past 5 years * Chemotherapy within the past 5 years * Prior intervention or surgery with intent to completely remove the target pathology Inclusion Criteria for Cohort 3: Patients will be ≥18 years of age, have a cervix and meet at least one of the following criteria: * History of current abnormal cervical/endocervical Pap test for which the patient is presenting for colposcopy * Cervical mass identified on physical exam and patient referred for cervical biopsy, even if colposcopy not recommended or indicated * Planned clinically indicated surgical excisional biopsy or removal of the cervix (cold knife cone, LEEP, hysterectomy) for abnormal Pap test, cervical dysplasia, cervical mass, or biopsy-proven invasive cervical cancer (adenocarcinoma, squamous cell carcinoma, adenosquamous carcinoma, or less common primary cervical carcinomas all eligible) Exclusion Criteria for Cohort 3: * History of pelvic or vaginal radiotherapy * Prior total hysterectomy (cervix removed) for any indication * Current known pregnancy diagnosis * Cervical mass biopsy-proven to be EC or a cancer metastatic from a non-cervical origin * Any prior cancer (except basal cell skin cancer) within the past 5 years * Chemotherapy within the past 5 years * Patients presenting for colposcopy as part of lower genital tract dysplasia or cancer surveillance after prior curative intent treatment and no current Pap abnormality or cervical mass * Prior intervention or surgery with intent to completely remove the target pathology for the current lesion / diagnosis during the current episode Inclusion Criteria for Cohort 4: Patients will be ≥45 years of age and should meet at least one of the following criteria: * Undergoing hysterectomy with biopsy-proven or clinically presumed (based on imaging and/or clinical symptoms) benign gynecologic or uterine pathology of fibroids, endometriosis, adenomyosis, or benign endometrial polyps. * Undergoing any gynecologic surgery in which a benign pathologic tissue diagnosis of fibroids, endometriosis, adenomyosis, or benign endometrial polyp is anticipated to be confirmed. Exclusion Criteria for Cohort 4: * Endometrial biopsy or office hysteroscopy within 2 weeks preceding the planned gynecologic surgery procedure for fibroids, endometriosis, benign endometrial polyps, or adenomyosis * Any surgery within the past 3 months * Prior hysterectomy * Current known pregnancy diagnosis * Prior or current biopsy-proven gynecologic cancer * Current biopsy-proven AEH/EIN, cervical, vaginal, or vulvar dysplasia * Prior pelvic or vaginal radiotherapy * Any prior cancer (except basal cell skin cancer) within the past 5 years * Chemotherapy within the past 5 years * Undergoing hysterectomy for prolapse without a coexisting known or presumed benign uterine pathologic diagnosis of fibroids, endometriosis, benign endometrial polyps, or adenomyosis * Prior intervention or surgery with intent to completely remove the target pathology for the current lesion / diagnosis during the current episode Inclusion Criteria for Cohort 5: Patients with a uterus will be ≥45 years of age and should meet the following criteria: * Presenting for GYN wellness exam ± Pap test * No change in medical conditions, new diagnoses, or new medications within the past 6 months Exclusion Criteria for Cohort 5: * Pap test or cervical biopsy within the past 1 month * Endometrial biopsy or office hysteroscopy within the past 1 month * Any surgery within the past 3 months * Prior hysterectomy * Current known pregnancy diagnosis * Prior or current biopsy-proven gynecologic cancer * Current biopsy-proven AEH/EIN, cervical, vaginal, or vulvar dysplasia * Prior pelvic or vaginal radiotherapy * Any prior cancer (except basal cell skin cancer) within the past 5 years * Chemotherapy within the past 5 years * Criteria met for inclusion in any of the other study cohorts Inclusion Criteria for Cohort 6: Patients ≥50 years of age and: * Postmenopausal * At least 1 intact ovary * Diagnosis of an adnexal mass or a clinical suspicion of early-stage ovarian cancer (including fallopian tube cancer) * Planned surgery for the adnexal mass * For vaginal fluid collection, patient must have a uterus, cervix and at least 1 intact fallopian tube* (without prior tubal ligation/occlusion) Exclusion criteria for Cohort 6: * Any current or prior cancer diagnosis (except basal cell or squamous cell skin cancer, non-gyn) * Chemotherapy for cancer treatment within the past 5 years prior to collection * Clinically suspected advanced stage ovarian cancer (Stage III or IV) on presentation, if known prior to specimen collection * Surgical candidates for recurrent ovarian cancer * History of pelvic or vaginal radiation therapy * Known current synchronous endometrial cancer or hyperplasia * Known current cervical, vaginal, or vulvar dysplasia Inclusion criteria for Cohort 7: Women will be ≥18 years of age and meet the following criteria: * Presence of clinically probable ovarian, fallopian tube, or primary peritoneal cancer (all under the umbrella of OC) based on clinical findings of any/all of the following: imaging showing adnexal and/or abdominal masses consistent with probable ovarian cancer, omental caking, elevated CA125, ascites, imaging-guided biopsy consistent with OC pathology * Newly diagnosed with ovarian, fallopian tube or primary peritoneal cancer without neoadjuvant therapy * At least one intact ovary * For vaginal fluid collection, patient must have a uterus, cervix and at least 1 intact fallopian tube* (without prior tubal ligation/occlusion) Exclusion criteria for Cohort 7: * Patients with recurrent OC * Any current or prior cancer diagnosis (except basal cell or squamous cell skin cancer, non-gyn) within the past 5 years * Chemotherapy for cancer treatment within the past 5 years prior to collection * History of pelvic or vaginal radiation therapy * Known current synchronous endometrial cancer or hyperplasia * Known current cervical, vaginal, or vulvar dysplasia * Current known pregnancy diagnosis

Conditions & Interventions

Interventions:

DIAGNOSTIC_TEST: Vaginal Fluid Collection, DIAGNOSTIC_TEST: Blood Collection

Conditions:

Endometrial Cancer, Cervical Cancer, Atypical Endometrial Hyperplasia, Cervical Dysplasia, Adnexal Mass, Ovarian Cancer

More Information

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