Self-collection for HPV Testing to Improve Cervical Cancer Prevention (SHIP) Trial (LMI-001-A-S02)

Status: RECRUITING

Eligibility Criteria

Age: 25 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Willingness and ability to provide a documented informed consent * Is 25 years or older * Has an intact cervix * Has had a referral for colposcopy and/or cervical excisional procedure in which routine cervical cancer screening has included HPV testing (HPV primary screening, co-testing, or atypical squamous cell of undetermined significance \[ASC-US\] cytology triage) or abnormal cytology performed within the past 12 months preceding the referral visit * Willing and able to undergo colposcopy, and if clinically indicated for standard of care (SOC) purposes, a biopsy, endocervical curettage, and/or a cervical excisional procedure, as applicable

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Exclusion Criteria:

* Is pregnant when presenting for the referral visit or gave birth within the past 3 months * Has a known history of excisional or ablative therapy to the cervix (e.g., loop electrosurgical excision procedure \[LEEP\], cone biopsy, cervical laser surgery, cryotherapy, thermal ablation) in the last 12 months prior to the referral visit * Has had a complete or partial hysterectomy, either supracervical or involving removal of the cervix, via self-report or confirmation via medical records * Known medical conditions that, in the opinion of the investigator, preclude study participation * Previous participation in the SHIP Trial. Participation is defined as completing the self-collection * Is experiencing unusual bleeding or pelvic pain

Conditions & Interventions

Interventions:
PROCEDURE: Biospecimen Collection, PROCEDURE: Cervical Biopsy, PROCEDURE: Colposcopy, OTHER: Electronic Health Record Review, PROCEDURE: Endocervical Curettage, PROCEDURE: Excision, PROCEDURE: HPV Self-Collection, PROCEDURE: Human Papillomavirus Test, OTHER: Questionnaire Administration, OTHER: Survey Administration
Conditions:
Cervical Carcinoma, Human Papillomavirus Infection

More Information

Contact(s): ctrrecruit@vcu.edu
Principal Investigator:
Phase: NA
IRB
Number:
System ID: NCT06611553
