

Validation study for the WID-qEC test in women undergoing hysterectomy: A diagnostic accuracy study

Submission date 29/01/2025	Recruitment status Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 10/02/2025	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 21/01/2026	Condition category Cancer	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

The POPCORN study will analyze the performance of the WID-qEC diagnostic test for endometrial carcinoma.

Who can participate?

All women undergoing hysterectomy at the University Hospital in Bern, Switzerland

What does the study involve?

The participants will be asked to undergo a WID-qEC test before their operation during their visit where a vaginal examination is planned. After that, the planned hysterectomy will be performed, no matter the underlying disease. The WID-qEC test results will then be compared to the histology results of the hysterectomy to evaluate the accuracy of the test and try to identify confounding factors.

What are the possible benefits and risks of participating?

There are no foreseen possible benefits from participation. The risks are slight bleeding at the site of sampling in the vagina, although this is very rare.

Where is the study run from?

Inselspital Bern, Switzerland

When is the study starting and how long is it expected to run for?

January 2025 to December 2026

Who is funding the study?

The labor team w in St. Gallen, Switzerland, provides the tests without cost to patients

Who is the main contact?

Franziska Siegenthaler MD, franziska.siegenthaler@insel.ch

Contact information

Type(s)

Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

Nil known

Study information

Scientific Title

PrOsPective observational COHoRt study on the performaNce of the WID-qEC test in patients undergoing hysterectomy

Acronym

Popcorn

Study objectives

This study evaluates the sensitivity and specificity of the WID-qEC test to evaluate its performance and identify factors that influence its performance.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 29/01/2025, Cantonal Ethics Committee for Research Bern (Rathausgasse 1, Bern, 3011, Switzerland; +41 31 633 70 70; mario.amacker@be.ch), ref: 2024-02365

Study design

Non-randomized diagnostic accuracy study

Primary study design

Observational

Study type(s)

Diagnostic, Safety

Health condition(s) or problem(s) studied

Performance of the WID-qEC test to accurately detect endometrium carcinoma in women who undergo planned hysterectomy

Interventions

The WID-qEC test is used before the hysterectomy in a non-randomised allocation. The results of the WID-qEC test will be compared with the final histology to evaluate sensitivity and specificity.

Patients are sampled consecutively when they have a planned total hysterectomy at University Hospital in Bern. There has been no Standard Test up till now, the nearest to fulfill this description is a transvaginal ultrasound. Therefore, the index Test (WID-qEC Test) is not compared to standard testing. The performance of the transvaginal ultrasound and the WID-qEC Test is mainly used when the symptom of postmenopausal bleeding occurs. However, the transvaginal ultrasound will not be replaced by the WID-qEC test. It is thought to be an additional diagnostic tool to prevent further interventional diagnostics such as a hysteroscopy which is mostly unnecessary (in case of non-malignant bleeding). There is no follow-up after the test has been taken.

Intervention Type

Device

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

WID-qEC test

Primary outcome(s)

The sensitivity and specificity of the WID-qEC test result measured using samples obtained from the cervicovaginal region immediately before the hysterectomy for the detection of endometrial /cervical cancers compared to a histology hysterectomy specimen

Key secondary outcome(s)

1. The underlying pathology of the ectocervix, cervical canal, endometrium and fallopian tube (and if also removed the ovary) in patients whose WID-qEC test (measured using histopathology of samples obtained from the cervicovaginal region immediately before the hysterectomy) is a false positive (i.e. WID-qEC test is positive in the absence of cancer in the hysterectomy/adnexal specimen).
2. The underlying pathology of the ectocervix, cervical canal and endometrium in patients whose WID-qEC test (measured using histopathology of samples obtained from the cervicovaginal region immediately before the hysterectomy) is a false negative (i.e. WID-qEC test is negative despite the presence of an invasive cancer in the cervix or the endometrial cavity).
3. To compare the level of the sum of the percentage of fully methylated reference (PMR) values

of the WID-qEC test (using samples obtained from the cervicovaginal region immediately before the hysterectomy) with the immunohistochemical markers assessed in the cancerous endometrium (p53, MMR markers, Ki67) or non-cancer patients (Ki67 only) in the normal endometrium or the most advanced hyperplastic lesion.

Completion date

31/12/2026

Eligibility

Key inclusion criteria

Undergoing total hysterectomy at University Hospital Bern, CH

Participant type(s)

Population

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 years

Upper age limit

100 years

Sex

Female

Total final enrolment

0

Key exclusion criteria

1. Lack of capacity to provide written informed consent
2. Refusal to participate in the study
3. Presence of medical conditions contraindicating general anesthesia

Date of first enrolment

03/03/2025

Date of final enrolment

31/12/2026

Locations

Countries of recruitment

Switzerland

Study participating centre
Inselspital Bern, University Hospital Bern
Friedbühlstrasse 19
Bern
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3011

Sponsor information

Organisation
University Hospital of Bern

ROR
<https://ror.org/01q9sj412>

Funder(s)

Funder type
Industry

Funder Name
labor team w ag

Funder Name
Women's Clinic Inselspital Bern

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date