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

Submission date
29/01/2025

Recruitment status
Recruiting

Registration date
10/02/2025

Overall study status
Ongoing

Last Edited
10/03/2025

Condition category
Cancer

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] 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 January 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

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Prospective diagnostic accuracy study

Study setting(s)
Hospital, Laboratory

Study type(s)
Diagnostic, Safety

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
WID-qEC test

Primary outcome measure

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

Secondary outcome measures
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.

Overall study start date
01/01/2025

Completion date
31/01/2026

Eligibility

Key inclusion criteria
Undergoing total hysterectomy at University Hospital Bern, CH

Participant type(s)
Population

Age group
Mixed

Lower age limit
18 Years

Sex
Female

Target number of participants
350

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
31/01/2026

Locations

Countries of recruitment
Switzerland

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

Sponsor information

Organisation
University Hospital of Bern

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
https://www.insel.ch/de/

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

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
01/02/2027

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date.

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