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# Self-collected versus clinician-collected cervical samples for the detection of HPV infections

**Submission date**
10/12/2020

**Recruitment status**
No longer recruiting

**Registration date**
15/12/2020

**Overall study status**
Completed

**Last Edited**
10/08/2022

**Condition category**
Cancer

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

## Plain English summary of protocol

Background and study aims
Cervical cancer is a major public health problem and is the second most common cancer in women living in less developed regions. There were an estimated 570 000 new cervical cancer cases in 2018. According to the World Health Organization, approximately 311 000 women died from cervical cancer in 2018, with more than 85% of these deaths occurring in low- and middle-income countries. In Mexico, cervical cancer is the third most common cancer among women.

Infection by high-risk Human Papillomavirus (HPV) of the cervicovaginal tract is known to be the major cause of cervical cancer. HPV-detection in clinician-collected cervical samples has been proven to be better than cervical cytology as a primary screening method for the prevention of cervical cancer.

Self-collection of cervical samples has been reported to be highly acceptable and preferred by most women.

This study aims to compare the performance of a device for patient self-collected samples to a device for clinician-collected samples in the detection of cervical cancer.

Who can participate?
Sexually active women, aged 30-65, with no history of medical or surgical treatment for cervical cancer, who are not pregnant or breastfeeding, are eligible to participate in the study.

What does the study involve?
The study involves using the self-sampling of cells from cervix/vagina using a self-sampling device (XytoTest) and attending a gynecological exam by a clinician who will use the professional-use device (Cervex-Brush). Both samples will be tested for HPV. The participants will also be asked their opinions on the acceptability of the self-collected samples method.

What are the possible benefits and risk of participating?
Participants may benefit from the possible detection of HPV which makes it possible to follow-up and treat precancer before the development of cervical cancer.

No additional risks are anticipated.

Where is the study run from?
Oncology clinic of Eduardo Liceaga, Mexico General Hospital (Mexico)

When is the study starting and how long is it expected to run for?
From January 2018 to May 2019

Who is funding the study?
The General Hospital of Mexico (Mexico). Abbott Laboratories, Division of Scientific Global Affairs (US) donated the HPV DNA reagents to complete the study. PreTect AS (Norway) provided HPV mRNA kits at reduced research cost. Mel- Mont Medical (US) the manufacturer of the XytoTest device, provided the self-collection device and all necessary consumables for the study.

Who is the main contact?
Dr. Sveinung Wergeland Sorbye
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# Contact information

### Type(s)
Scientific

### Contact name
Dr Sveinung Wergeland Sorbye

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# Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
CI/243/18

# Study information

### Scientific Title
Self-collected versus clinician-collected cervical samples for the detection of HPV infections by 14-type DNA and 7-type mRNA tests

### Acronym
Mía

### Study objectives
1. The self sampling device XytoTest (Mel-Mont Medical, US) and clinician-collected samples by Cervex-Brush (Rovers Medical Devices, Oss, the Netherlands) can both be used to collect sufficient material for both primary HPV-testing with direct molecular triage
2. Self-collected and clinician-collected samples for HPV detection will show good concordance

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Approved 04/07/2018, the institutional ethics review board at Eduardo Liceaga (General Hospital of Mexico, Dr. Balmis No.148, Col. Doctores, Delegación Cuauhtémoc, Mexico City, PC 06720, Mexico; +52-55-5460-5144; no email contact available), ref: CI/243/18

### Study design
Single centre observational case series

### Primary study design
Observational

### Secondary study design
Case series

### Study setting(s)
Hospital

### Study type(s)
Screening

### Participant information sheet
Not avaliable in web format, please use contact detalis to request a participant information sheet.

### Health condition(s) or problem(s) studied
Cervical cancer, human papillomavirus (HPV) infection

### Interventions

All women were screened by both self-sampling (using XytoTest) and clinician collected cytology (using ThinPrep). Both samples were HPV tested with HPV DNA (Abbott) and HPV mRNA (Proofer 7). All women with a positive HPV test result were followed-up according to the national guidelines in Mexico. The results of the two devices were recorded during the period of August 2018 to April 2019. No follow-up data will be collected.

### Intervention Type
Device

### Phase
Not Applicable

### Primary outcome measure
1. HPV test result for samples collected from the same patient using both the XytoTest and ThinPrep sampling devices measured using an HPV DNA test (Abbott RealTime HR HPV test) and an HPV mRNA test (PreTect HPV-Proofer 7) at a single timepoint

### Secondary outcome measures
1. Patient-reported acceptability of the self-collected samples method measured using a four-question questionnaire directly after self-testing using the XytoTest device

### Overall study start date
01/01/2018

### Completion date
01/05/2019

## Eligibility

### Key inclusion criteria
1. Sexually active women
2. Aged between 30 and 65 years
3. Responded positively to the invitation

### Participant type(s)
Healthy volunteer

### Age group
Adult

### Sex
Female

### Target number of participants
505

### Total final enrolment
505

### Key exclusion criteria
1. Pregnant or breastfeeding
2. Sexual activity ≤24 h before the collection of samples
3. History of medical or surgical treatment (radiotherapy, chemotherapy, hysterectomy, or cone biopsy) for cervical cancer

### Date of first enrolment
01/08/2018

### Date of final enrolment
01/05/2019

## Locations

### Countries of recruitment
Mexico

### Study participating centre
**Hospital General de México "Eduardo Liceaga"**
Dr. Balmis No.148
Col. Doctores
Delegación Cuauhtémoc
Mexico City
Mexico
06720

## Sponsor information

### Organisation
Hospital General de México

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### Sponsor type
Hospital/treatment centre

### Website

https://hgm.salud.gob.mx/

**ROR**
https://ror.org/01php1d31

# Funder(s)

**Funder type**
Hospital/treatment centre

**Funder Name**
Hospital General de México

# Results and Publications

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

**Intention to publish date**
01/02/2021

**Individual participant data (IPD) sharing plan**
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr. Sveinung Wergeland Sorbye (sveinung.sorbye@unn.no). The data is in a Microsoft Excel sheet (patient number, age, results of the four questions' questionnaire, and HPV DNA results and HPV mRNA results in patient collected and clinician collected samples. The data will be available after publication and in 10 years (until 01/02/2031). All patients will sign informed consent. The dataset is anonymized.

**IPD sharing plan summary**
Available on request

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Basic results | | 13/12/2020 | 04/01/2021 | No | No |
| Results article | | 31/05/2021 | 02/06/2021 | Yes | No |
| Protocol file | | | 10/08/2022 | No | No |