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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
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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