

# The development and evaluation of an artificial intelligence (AI) image recognition device to improve cervical pre-cancer screening and management in low- and middle-income countries

<b>Submission date</b> 17/07/2020	<b>Recruitment status</b> Recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 04/09/2020	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 27/06/2025	<b>Condition category</b> 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

Cervical cancer is a disease of unscreened populations, many of whom are socio-economically disadvantaged. In this research project we are trying out a new technology that we expect to detect cervical pre-cancer and cancer more efficiently than the existing technologies. We will use a device (n-AVE) that will take high-quality pictures of the cervix and will use a computer programme (artificial intelligence) to give the diagnosis. Similar technology was recently tested in a study in the National Cancer Institute of USA and was observed to be highly successful in detecting cervical abnormalities. The technology that we are going to test is still under development.

### Who can participate?

The women aged between 30 to 59 years attending the selected screening clinics with no history of cervical cancer and with a recent abnormal screening test will be invited to participate in this research project.

### What does the study involve?

The participants agreed to participate in the study, will be interviewed by a social worker to collect basic personal data (contact details, age, education, occupation, marital status and number of pregnancies). A doctor will examine the participants with n-AVE (the new device). During examination the doctor will clean the cervix with saline and take pictures after magnifying the cervix. Then he/she will apply dilute vinegar and take pictures. Finally, iodine will be applied to the cervix and again pictures will be taken. By looking at the pictures the doctor will decide if a biopsy is needed to be taken from the cervix. The participants will be advised treatment by the doctor based on the examination if the biopsy

results are abnormal. If the HPV test is positive but other tests are normal, participants will be advised to have the examination repeated after one year. If the HPV test is negative, no cervical screening is necessary in next 5 years.

What are the possible benefits and risks of participating?

The participants will get the benefits of having cervical cancer screening, treatment if necessary, and follow up by participating in the project. The tests and the treatment procedures will be done free of cost. The research will greatly benefit all women by identifying the most suitable and effective method of detecting cervical precancers and cancers and your participation is very important to us. Irrespective of the test method, the participants may expect any of the following side effects after examination:

- Vaginal discomfort: During gynecological examination an instrument (speculum) is introduced in the vagina. This may cause some discomfort during the examination
- Vaginal discharge: Some women complain of watery discharge for a day or two after cervical examination most likely due to the use of light vinegar. The discharge does not cause any inconvenience and stops of its own.
- Vaginal bleeding: Some of the women have vaginal spotting for a few days after examination especially after taking biopsy. This stops on its own and usually no treatment is necessary. The n-AVE procedure will prolong the routine screening examination time by approximately 5 minutes.

Where is the study run from?

The study will be conducted in the field clinics for cervical cancer screening or colposcopy clinics of the following institutions:

1. All India Institute of Medical Sciences, New Delhi, India
2. Chittaranjan National Cancer Institute, Kolkata, India
3. Adyar Cancer Center, Chennai, India
4. National Cancer Institute, Bangkok, Thailand

When is the study starting and how long is it expected to run for?  
December 2019 to November 2027

Who is funding the study?

Intramural funds from IARC and participating institutions

Who is the main contact?

Dr Partha Basu, basup@iarc.fr

## Contact information

**Type(s)**

Scientific

**Contact name**

Dr Partha Basu

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**Type(s)**

Public

**Contact name**

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## Additional identifiers

**EudraCT/CTIS number**

Nil known

**IRAS number****ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

IEC 19-33

## Study information

**Scientific Title**

Systematic and Automated Visual Evaluation of Cervix

**Acronym**

SAVE-Cervix

**Study objectives**

The device requires further fine tuning to be able to accurately discriminate between normal /low grade and high grade or cancer. We hypothesize that training this classifier on more images, in particular, specifically targeted images prospectively captured by the device, will improve its accuracy and generalizability to predict abnormality of the cervix in new images collected from different settings and locations. The current model will be tested as a combined screening and

diagnostic device in real field setting to identify high grade lesions, direct biopsy and assist treatment decision making. This baseline efficacy data will help us improve the artificial intelligence algorithm further.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

1. Approved 05/12/2019, IARC Ethics Committee (IARC Ethics Committee: 150 cours Albert Thomas, 69372 Lyon cedex 08, France; +33 (0)4 72 73 83 41; iec-secretariat@iarc.fr), ref: IEC 19-33
2. Approved 12/02/2020, Institute Ethics Committee (All India Institute of Medical Sciences: Room No 102, 1st Floor Old O.T. Blocks, Ansari Nagar, New Delhi 110029, India; +91 33 2659 4574; no email provided), ref: IEC-73/07.02.2020
3. Approved 30/10/2019, Institute Ethics Committee (Chittaranjan National Cancer Institute: 37, S.P. Mukherjee Road, Kolkata, 700026, WB, India; +91 33 2475 7606; no email provided), ref: CNCI- IEC-RM-2019-13
4. Approved 20/02/2020, NCI Thai Ethics Committee (National Cancer Institute of Thailand, 6268 /1 Thanon Rama VI, Thung Phaya Thai, Ratchathewi, Bangkok 10400, Thailand; +66 2 202 6800; no email provided), ref: EC COA 007/2020

### **Study design**

Multicentre observational cross-sectional study

### **Primary study design**

Observational

### **Secondary study design**

Cross sectional study

### **Study setting(s)**

Hospital

### **Study type(s)**

Screening

### **Participant information sheet**

Not available in web format, please use the contact details to request a patient information sheet

### **Health condition(s) or problem(s) studied**

Cervical cancer screening

### **Interventions**

The new technology will be evaluated in a field trial as a screening device (compared to standard of care HPV test), triaging device for HPV positive women (compared to colposcopy) and a diagnostic device. The 'gold standard' for comparison will be histopathology of cervix. Women between 30 and 59 years of age attending the clinics at the study sites for cervical cancer screening or for colposcopy will be invited to participate and will be recruited after signing informed consent. They will have sample collection for HPV test (if not screened already) followed by examination with the new device. The new device is just like a mini-colposcope and

uses the same steps and principles as colposcopy to detect cervical precancers and cancers. The diagnosis will be made by the clinician based on the acquired images and they will be masked to the AI based diagnosis generated by the device.

All women with positive HPV test and/or abnormal colposcopy will have a biopsy taken from the cervix. AI based diagnosis will be compared to HPV test (to see how the AI compares to HPV test as a screening test), to colposcopy (to see how AI performs as a triaging test) and histopathology (final disease verification). The images collected will be stored, annotated and used for further training the deep machine learning.

## **Intervention Type**

Device

## **Phase**

Phase II

## **Drug/device/biological/vaccine name(s)**

N-AVE

## **Primary outcome measure**

1. Accuracy of AI based algorithm in detecting cervical high grade lesion is measured by estimating the specificity and sensitivity with histopathology as gold standard, after all the cases are recruited and investigated
2. The agreement between the investigational device and a colposcopist to correctly identify the transformation zone will be calculated from the data capture from all the study subjects, after all the cases are recruited and investigated

## **Secondary outcome measures**

There are no secondary outcome measures

## **Overall study start date**

01/06/2019

## **Completion date**

30/11/2027

# **Eligibility**

## **Key inclusion criteria**

1. All consenting women aged between 30 to 59 years of age
2. With no cervical cancer screening in last 3 years (if recruited at screening clinics)
3. With recent abnormal screening test (when recruited at the colposcopy clinics)
4. The centers in India will recruit women eligible and willing to undergo cervical cancer screening in the community and/or hospital outpatients
5. The centers outside India will recruit women at the colposcopy clinics where the women with abnormal screening tests (cytology, HPV test or VIA) are evaluated with colposcopy

## **Participant type(s)**

Healthy volunteer

## **Age group**

Adult

**Lower age limit**

30 Years

**Upper age limit**

59 Years

**Sex**

Female

**Target number of participants**

5,040

**Key exclusion criteria**

1. Refusal to participate; actively menstruating or pregnant
2. Inability to provide consent due to mental or debilitating illness
3. Previously detected with cervical precancer or cancer

**Date of first enrolment**

01/12/2019

**Date of final enrolment**

30/06/2027

## **Locations**

**Countries of recruitment**

India

Thailand

**Study participating centre**

**All India Institute of Medical Sciences**

Department of Obstetrics & Gynaecology

Room 3101, 3rd floor, Teaching Block

Ansari Nagar

New Delhi

India

110029

**Study participating centre**

**Chittaranjan National Cancer Institute (CNCI)**

37, S.P. Mukherjee Road

Department of Gynecologic Oncology

Kolkata  
India  
700026

**Study participating centre**

**Tata Memorial Center**

Dr. E Borges Road  
Parel  
Mumbai  
India  
400 012

**Study participating centre**

**Mount St. John's Medical Centre**

4586+RCM  
Michael's Mount  
St John's  
Antigua and Barbuda  
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## **Sponsor information**

**Organisation**

International Agency For Research On Cancer

**Sponsor details**

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**Sponsor type**

Research organisation

**Website**

<http://www.iarc.fr/>

**ROR**

<https://ror.org/00v452281>

# Funder(s)

## Funder type

Research organisation

## Funder Name

Centre International de Recherche sur le Cancer

## Alternative Name(s)

International Agency for Research on Cancer, Agencia Internacional de Investigación sobre el Cáncer, CIRC, IARC

## Funding Body Type

Government organisation

## Funding Body Subtype

Research institutes and centers

## Location

France

## Funder Name

All-India Institute of Medical Sciences

## Alternative Name(s)

AIIMS

## Funding Body Type

Government organisation

## Funding Body Subtype

Local government

## Location

India

## Funder Name

Chittaranjan National Cancer Institute

## Funder Name

Cancer Institute (WIA) Chennai

**Funder Name**

National Cancer Institute (Bangkok)

## **Results and Publications**

**Publication and dissemination plan**

Planned publication in a high-impact peer-reviewed journal.

**Intention to publish date**

31/12/2025

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

**IPD sharing plan summary**

Available on request