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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

Submission date 17/07/2020	**Recruitment status** Recruiting	[_] Prospectively registered [_] Protocol
Registration date 04/09/2020	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 27/06/2025	**Condition category** Cancer	[_] Individual participant data [X] 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

ORCID ID
https://orcid.org/0000-0003-0124-4050

Contact details

International Agency for Research on Cancer
150 cours Albert Thomas
Lyon
France
69372
+33 472738167
basup@iarc.fr

Type(s)
Public

Contact name
Dr Partha Basu

Contact details
International Agency for Research on Cancer
150 cours Albert Thomas
Lyon
France
69372
+33 472738167
basup@iarc.fr

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
-

Sponsor information

Organisation
International Agency For Research On Cancer

Sponsor details
150 cours Albert Thomas
Lyon
France
69372
+33 472738485
terrassev@iarc.fr

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