

Cervical Swede score screening by colposcope and the Gynocular

Submission date 13/09/2013	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 20/01/2014	Overall study status Completed	☐ Statistical analysis plan
		☒ Results
Last Edited 03/07/2015	Condition category Urological and Genital Diseases	☐ Individual participant data

Plain English summary of protocol

Background and study aims

A colposcope is a microscope which is adapted for vaginal examination and helps doctors to detect abnormal areas on the cervix that might harbour the early stages of cervical cancer. This study aims to find out if a battery-driven handheld colposcope, the Gynocular, is equally good at detecting cervical lesions as a stationary colposcope.

Who can participate?

Women referred for colposcopy at the Colposcopy Clinic of Bangabandhu Sheikh Mujib Medical University (BSMMU).

What does the study involve?

Participants were randomly allocated to one of two groups: the participants in Group 1 were screened using the Gynocular and the participants in Group 2 were screened using the stationary device. Participants then swapped over - those allocated to Group 1 were examined with the stationary colposcope and Group 2 were examined using the Gynocular. All women found to have cervical lesions were offered treatment at BSMMU.

What are the possible benefits and risks of participating?

Participating in the study involved no side effects. There were no risks of participating. If a woman chose not to participate, she had a standard method of examination.

Where is the study run from?

The study ran from the Department of Colposcopy, BSMMU, Dhaka, Bangladesh.

When is the study starting and how long is it expected to run for?

The study started in June 2012 and ended in September 2013.

Who is funding the study?

The study was funded by Gynius AB (Sweden) and H&M Conscious Foundation (Sweden).

Who is the main contact?

Prof Ashrafun Nessa

ashra58@yahoo.co.uk

Contact information

Type(s)

Scientific

Contact name

Prof Ashrafun Nessa

Contact details

Department of Obstetrics and Gynecology

Bangabandhu Sheikh Mujib Medical University Hospital (BSMMU)

Shabag

Dhaka

Bangladesh

1000

Additional identifiers

Study information

Scientific Title

The Bangladesh Swede score Gynocular clinical trial

Study objectives

Cervical Swede score as an alternative cervical screening approach in low-resource settings by using a pocket-sized battery-driven colposcope, the Gynocular.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The study was approved by the local ethics committees in Bangladesh and in Sweden:

1. The Institutional Review Board of BSMMU (Dnr BSMMU/2012/3176)
2. Stockholm Regional Ethical Review Board (Dnr 2012/545-31/1)

Primary study design

Interventional

Study design

Crossover randomized clinical trial

Study type(s)

Screening

Health condition(s) or problem(s) studied

Cervical screening
Colposcopy
Swede score

Interventions

Patients were randomized to two groups:

Group 1 were examined with the hand-held colposcope, the Gynocular

Group 2 were examined with a stationary colposcope

Participants were then crossed over. Those randomized to Group 1 were examined with the stationary colposcope and Group 2 were examined using the Gynocular. Women who had a positive cytology or cervical biopsy with high-grade cervical dysplasia were offered treatment at BSMMU.

Intervention Type

Device

Primary outcome(s)

Compare if a hand-held colposcope, the Gynocular, could detect cervical lesions equal to a stationary colposcope

Key secondary outcome(s)

To evaluate the performance of Swede score to detect cervical lesions in VIA-positive women, and detection rates of HPV

Completion date

15/09/2013

Eligibility**Key inclusion criteria**

1. Women positive for acetic acid (VIA) at opportunistic screening by trained family welfare visitors, senior staff nurses and doctors in the Dhaka region, Bangladesh, referred for colposcopy at the Colposcopy Clinic of Bangabandhu Sheikh Mujib Medical University (BSMMU). A women is considered to be VIA positive when a trained doctor or nurse noticed sharp, distinct, well defined, dense acetowhite areas on the cervix, with or without raised margins, close to the squamocolumnar junction (SCJ) in the transformation zone 6-9, 15.
2. Women signing an informed consent to participate in the study after receiving oral and written information from a social worker
3. Ability to understand written and oral information

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

1. Ongoing vaginal bleeding
2. Any previous gynecological examinations for at least one week before
3. Pregnancy

Date of first enrolment

01/06/2012

Date of final enrolment

15/09/2013

Locations**Countries of recruitment**

Bangladesh

Study participating centre

Bangabandhu Sheikh Mujib Medical University Hospital (BSMMU)

Dhaka

Bangladesh

1000

Sponsor information**Organisation**

Gynius AB (Sweden)

ROR

<https://ror.org/04ykj1118>

Funder(s)**Funder type**

Industry

Funder Name

Gynius AB (Sweden)

Funder Name

H&M Conscious Foundation (Sweden)

Results and Publications

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

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	03/11/2014		Yes	No