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Cervical Swede score screening by colposcope and the Gynocular

Submission date
13/09/2013

Recruitment status
No longer recruiting

Registration date
20/01/2014

Overall study status
Completed

Last Edited
03/07/2015

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 women 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?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

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)

Study design

Crossover randomized clinical trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Screening

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

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

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

Overall study start date
01/06/2012

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

Age group
Adult

Sex
Female

Target number of participants
540

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)

Sponsor details
Döbelnsgatan 40
Stockholm
Sweden
111 40

Sponsor type
Industry

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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