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The use of a mini-colposcope, the Gynocular, to detect cervical lesions in women with abnormal cytology and high-risk human papillomavirus: a randomized, cross-over, non-inferiority trial

Submission date
08/12/2013

Recruitment status
No longer recruiting

Registration date
30/01/2014

Overall study status
Completed

Last Edited
30/01/2014

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Cervical cancer is diagnosed in 470,000 women a year worldwide and 273,000 women die of the disease, mostly where there is less helpaccess to healthcare. If detected early, many women can be cured of the disease. However, often women lack access to screening, diagnosis and treatment. Our aim is to compare the performance of a battery-driven colposcope, the Gynocular, to traditional stationary colposcopes in detecting the cervical cancer lesions.

Who can participate?
Women referred to undergo colposcopy to detect cervical lesions can take part in this study.

What does the study involve?
Women are randomly allocated to undergo examination using either the Gynocular or the traditional colposcope. A sample from the cervix is taken from all women for further analysis. The performance of the two instruments are is analysed.

What are the possible benefits and risks of participating?
There are no risks to the women in participating in the study.

Where is the study run from?
1. Department of Obstetrics and Gynecology, Danderyd Hospital, Sweden
2. Department of Clinical Sciences, Karolinska Institute (Karolinska Institutet), Stockholm, Sweden.

When is the study starting and how long is it expected to run for?
The study ran from June 2012 to July 2013.

Who is funding the study?
The H&M Conscious Concious Foundation (Sweden) and Gynius AB (Sweden) funded the study.

Who is the main contact?
Dr Helena Kopp Kallner

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
A comparison of the performance of the Gynocolar and stationary colposcope by the Swede score colposcopy system in women with abnormal cytology: a randomized cross-over trial

Acronym
ARTEMIS

Study objectives
A pocket-sized mini-colposcope magnifier (Gynocular) is equally good at detecting cervical lesions compared to a stationary colposcope.

Primary study aim: to demonstrate that the Gynocular magnifier is non-inferior to a stationary colposcope in finding acetowhite cervical lesions during examination in women with precancerous cervical dysplasia.

Secondary study aim: to show that the Gynocular magnifier is non-inferior to a colposcope with regard to sensitivity and specificity in finding cervical intraepithelical neoplasia (CIN) verified in cervical biopsies.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Stockholm Regional Ethical Review Board, 10/04/2010, Dnr: 2013/1855-3 and 2009/2032-31/1
2. The Medical Products Agency of Sweden, 31/10/2013, Dnr: 461:2010/502414.

Study design
Randomized cross-over trial

Primary study design
Interventional

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Colposcopy and cervical dysplasia

Interventions
Women will be randomly allocated in blocks of clinic day to start the examination with either the stationary colposcope or the Gynocular. Then, the woman will be examined by the same examiner with the second instrument in order to assess the performance of agreement between the two instruments.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Each patient will be assessed by the Swede score systematic colposcopy system, where each of five colposcopic variables (acetowhiteness, margins plus surface, vessel pattern, lesion size and iodine staining) are given a score of 0, 1 or 2 points. All women will also have a liquid-based cytology specimen taken at the time of examination using a plastic spatula on the cervix and a cervix brush in the cervical canal. The examination will be finalized with one or more biopsies taken from areas of suspected cervical lesions when the Swede score is above 0.

Key secondary outcome(s))
Not provided at time of registration

Completion date
01/07/2013

Eligibility

Key inclusion criteria
1. Women with atypical cells of undetermined significance (ASC-US) or low-grade squamous intraepithelial lesion (LSIL) and high-risk human papillomavirus (HPV) and HR HPV positivity, or any high grade lesion (CIN II or more) regardless of HPV status, referred for colposcopy to the Department of Obstetrics and Gynecology, Danderyd Hospital, Stockholm, Sweden between June 2012 and June 2013
2. Ability to understand written and oral information in Swedish
3. Willingness to sign informed consent to take part in the study after oral and written 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 within a week prior to the examination
3. Pregnancy

Date of first enrolment
01/06/2012

Date of final enrolment
01/07/2013

Locations

Countries of recruitment
Sweden

Study participating centre
Döbelnsgatan 23
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Sponsor information

Organisation
Gynius AB (Sweden)

ROR
https://ror.org/04ykj1118

Funder(s)

Funder type
Industry

Funder Name
H&M Conscious Foundation (Sweden)

Funder Name
Gynius AB (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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes