Reliability, validation and acceptance of a novel self-lavaging collection device, MySampleTM, in combination with the HPV-Risk Assay and QIAsure Methylation test to screen for cervical cancer.

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Cervix disorders (excl infections and inflammations)
Study type	Interventional

Summary

ID

NL-OMON46230

Source
ToetsingOnline

Brief title
CESSAR (CErvical Self Sampling Reliability)

Condition

- Cervix disorders (excl infections and inflammations)

Synonym
cervical cancer

Research involving
Human

Sponsors and support

Primary sponsor: Maxima Medisch Centrum
Source(s) of monetary or material Support: Maatschap Gynaecologie

Intervention

Keyword: cervical cancer, HPV-risk assay, national screening programme, Self-sampling

Outcome measures

Primary outcome

* To assess the reliability of MySample (MySample BV, the Netherlands) used in home-setting, for hrHPV testing and methylation triage (HPV-Risk Assay and QIAsure Methylation test, Selfscreen, the Netherlands), using the clinician-collected brush as comparative method by calculating percent agreement and the kappa, stratified for CIN2+/CIN3+.

* To clinically validate specimens self-collected with MySample by evaluating the sensitivity of hrHPV primary (HPV risk assay) for identifying CIN2+/CIN3+, as confirmed by colposcopy and biopsy. The relative sensitivity of hrHPV testing on MySample self-samples must be at least 90% compared to that of hrHPV testing on the clinician-collected brush samples as determined with the non-inferiority score test.

Secondary outcome

* To compare the sensitivity and specificity of methylation triage (HPV-Risk in combination with QIAsure Methylation test) and the specificity of primary hrHPV testing (HPV-Rrisk assay) between the MySample specimens and clinician-collected specimens for identifying CIN2+ and CIN3+, as confirmed by colposcopy and biopsy.

* To evaluate the acceptability of MySample compared to the pelvic examination;

* To evaluate the Instructions for Use;

* To evaluate the functionality of the novel MySample: the assembly of bottle

to inserter, technical complaints;

* To evaluate the acceptance, and validate the procedure to handle, store,

process the specimen in the laboratory;

* To measure the volume of fluid collected with MySample;

* To measure pellet size;

* To compare the percentage of indeterminate or insufficient specimen

collections between MySample and clinician-collected specimens by b-globin

testing;

* To record any adverse event that occurs from use of the device, as a

measurement of safety.

Study description

Background summary

Self-collection of cervicovaginal cells by lavage has been proved to give reliable results in HPV-screening on cervical cancer. Self-collection has been proved to increase the participation rate of women in screening programs and contributes to a substantial higher detection of women at risk of cervical cancer.
A novel lavage method, the MySample (MySample BV), is designed to improve the ease of use and comfort at use for women while keeping the lavage method itself unchanged.

Study objective

This study is to answer two questions. First the reliability and validity of the novel lavage method to screen on cervical cancer in combination with the clinically validated hrHPV and hypermethylation triage tests. Second the

functionality and acceptance of MySample, evaluated by the users (women and laboratory).

Study design

An anticipated 60 colposcopy with CIN2+ and 140 healthy volunteers in the age of 30-65 years old with an appointment at the gynecology outpatient department are invited to participate in the study. The colposcopy referrals will receive the self-sampler at an extra inclusion visit that takes place before colposcopy. The healthy volunteers will receive the self-sampler at home. Participants will collect a lavage sample at home and are requested to complete pre- and post-use questionnaires addressing the ease of use, degree of comfort, confidence and preference. Participants will also complete a technical questionnaire addressing the functionality of the novel device. In addition to a self-collected lavage specimen a clinician will collect a cervical smear at the hospital. The test results of the cervical specimen will be compared with those of the lavage specimen.
All collected specimens are sent to Self-screen B.V. labratorium (part of VU medical Center Amsterdam). Both the lavage and clinician-obtained specimen will get different patient codes to assure blinding of paired specimens. The laboratory will measure volume and pellet size of the lavage specimen. On both specimens the lab will test on hrHPV and beta-globin for quality control. All hrHPV positive specimens will subsequently be tested on methylation (triage). The outcome on both lavage and clinician specimen will be compared with each other.
All colposcopy test results collected within the study period will be included in the analysis. The lavage and clinician specimens will be compared on the sensitivity and specificity to identify CIN2+ women.

Intervention

nvt

Study burden and risks

Not applicable

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* Colposcopy referral (> PAP 3A2 in the cervical cancer screening program, or at the gynecological outpatient department) or healthy volunteer.
* Scheduled appointment at the gynecological outpatient department of the participating hospital;
* Between 30 and 65 years old;
* Self-report being able to read in Dutch;
* Willing to sign Informed Consent;

Exclusion criteria

* No uterus / history of complete hysterectomy;
* No previous treatment for CIN 2/CIN 3
* healthy volunteers; positive PAP-smear in the last 5 years.
* Mental or physical handicap that would prevent self-collection of specimens;* Women are not allowed to use the self-sampling device when they are menstruating. Participants who are having their period between recruitment and the scheduled appointment will be instructed to take this into consideration, allowing at least one week interval between self-collection and hospital visit.
* Women who use vaginal products (douche, spermicide, antifungal) will be instructed to wait

for 48 hours before using the device. This does not include water-based lubricants or condoms and the NuvaRing.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	200
Type:	Actual

Medical products/devices used

Generic name:	MySample
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	23-05-2016
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	29-05-2017
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

Approved WMO Date:	27-11-2017
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL55570.015.15