high risk HPV detection from urine and self-collected specimens as patient friendly alternative for physician taken smears

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Female reproductive tract infections and inflammations
Study type	Observational invasive

Summary

ID

NL-OMON48967

Source
ToetsingOnline

Brief title
HPV detection and stability from urine and self-collected specimens

Condition

- Female reproductive tract infections and inflammations

Synonym
Cervical dysplasia / Cervical cancer

Research involving
Human

Sponsors and support

Primary sponsor: Jeroen Bosch Ziekenhuis

Source(s) of monetary or material Support: Jeroen Bosch ziekenhuis

Intervention

Keyword: HPV, Self-collected specimens (Evalyn Brush), Stability in time, Urine

Outcome measures

Primary outcome

For both the self-collected specimens and urine the most optimal combination of HPV DNA/RNA isolation and detection will be determined. Stability of HPV DNA and RNA on the Evalyn Brush will be investigated by comparing results on timepoints T=0 and T=4 days. For urine, the effect of adding preservationmedium on stability of HPV DNA and RNA will be investigated. Furthermore, urine will be analysed on different timepoints (T=0, 4 and 7 days) to analyse stability of HPV. All obtained results from the self-collected specimens and urine will be compared to the results of the physician taken smear (routine diagnostics, golden standard).

Secondary outcome

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Study description

Background summary

Since 2017, the Dutch screeningsprogram for cervical cancer has changed. In the new screeningsprogram women are tested on the presence of human papillomavirus (HPV) in physician taken smears. A HPV-test (DNA-based) is more sensitive in detecting cervical changes. The new test detects more women with cervical abnormalities as compared to microscopical analysis of cervical cells. Not every woman feels comfortable to visit a physician for cervical sampling (physician taken smear). For these women, it is possible to request a self-sampling device (Evalyn Brush). Evalyn Brush samples are also tested for

HPV presence and in this way early detection of cervical changes is possible. The Evalyn Brush is already an accepted method and used in the Dutch screeningsprogram for cervical cancer (P. Ketelaars et al. 2017, M. Leinonen et al. 2018). Another option for HPV detection is urine. Both urine and/or a self-collected specimen of the cervix can serve as more patient-friendly ways of sampling. However, we don*t know how much urine, which DNA/RNA isolation method, and which HPV detection method will results in the most optimal HPV detection as compared to the physician taken smear (A. Vosters et al. 2014, A. Leeman et al. 2017, S. Van Keer et al. 2017).
Therefore, we want to ask non-pregnant HPV-positive patients (18 years or older) to sample 2 times with the Evalyn Brush and to collect urine by using the Collipee system. The Collipee system enables collection of first void urine. In this way, we can investigate with which method HPV is best detected. Furthermore, we can study HPV stability in time. This is necessary because it's unclear how fast women send self-collected samples to the screeningslaboratory. Results are compared with the results from the smears taken by the gynecologist.

Study objective

The main goal of this technical feasibility study is to investigate with which HPV isolation and detection method urine and the Evalyn Brush can be combined. HPV stability in urine and on the Evalyn Brush will be investigated as it*s unclear how fast women send self-collected samples to the laboratory. It*s unknown what the effect is on HPV detection when samples are not tested immediately.

1) Investigate if HPV DNA and/or RNA can be detected on the Evalyn Brush on timepoints T=0 and 4 days after sampling (determine if HPV degrades on Evalyn Brush in time).
2) Investigate which HPV detection method can be combined with the Evalyn Brush and which method provides most optimal results compared to the physician taken smear (gold standard).
3) Investigate if urine can be used for HPV DNA and/or RNA detection by comparing different isolation and detection methods.

Study design

Small technical feasibilty study to investigate different parameters: 1) sample type, 2) isolation methods, and 3) HPV detection methods. Gynecologist includes women and provides Collipee system and 2 Evalyn Brushes. Patient samples will be anonimised and labelled 1-10 for the researchers. Gynecologist can trace back results to patients. Patients will only be informed about diagnostic smear. Inclusion of women stops when both urine and 2 Evalyn Brushes of 10 women are collected. When a woman doesn*t provide urine, but she does provide 2 Evalyn Brushes than the brushes will be used for the study. More than 10 women will

then by included. When a woman does not want to participate in the study after providing samples, those samples or results will be excluded.

Study burden and risks

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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

HPV positive woman
18 years or older

Exclusion criteria

Pregnant
Under 18 years of age

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	25-01-2019
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	09-07-2018
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

Approved WMO

Date:	26-02-2020
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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	NL65866.028.18