# Validation of the dry Evalyn Brush, an improved cervicovaginal self-sampling device for HPV detection

Published: 12-10-2012
Last updated: 28-04-2024

This study will be conducted to determine the overall hr-HPV agreement between self-sampled cervicovaginal smear (Evalyn Brush) and physician-obtained samples taken by a trained physician (liquid based cervical smear) in a screening population. The...

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Cervix disorders (excl infections and inflammations) |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON35865

**Source**
ToetsingOnline

**Brief title**
Validation dry Evalyn Brush

### Condition

- Cervix disorders (excl infections and inflammations)

**Synonym**
cervical cancer, human papillomavirus

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Sint Radboud
**Source(s) of monetary or material Support:** Afdeling Verloskunde en Gynaecologie

## Intervention

**Keyword:** Cervical cancer, Screening, Self-sample device

## Outcome measures

### Primary outcome

The main study parameters are measuring the overall hr-HPV agreement between

self-sampled cervicovaginal smear (Evalyn Brush) and physician-obtained samples

taken by a trained physician (liquid based cervical smear).

### Secondary outcome

To determine the acceptability of the self-sample test.

# Study description

### Background summary

Primary screening on high-risk Human papillomavirus (hrHPV) will be the next step in prevention of cervical cancer. Women not attending screening are more likely to participate given the opportunity of self-sampling for hrHPV testing. The Evalyn Brush (Rovers, The Netherlands) is an improved user friendly and easy to use cervicovaginal self-sampling device which is developed according to user requirements of women. Before the Evalyn Brush may be used in cervical cancer screening, this self-sampling device has to be validated in a screening population.

### Study objective

This study will be conducted to determine the overall hr-HPV agreement between self-sampled cervicovaginal smear (Evalyn Brush) and physician-obtained samples taken by a trained physician (liquid based cervical smear) in a screening population. The acceptability of using this self-test will be determined.

### Study design

We will recruit women visiting the general practitioner for a regular cervical smear. All participants will meet the criteria for the national screening program for cervical cancer in the Netherlands. They are informed about the study by the general practitioner or the practice assistant. After informed

consent the participating women takes, before the regular cervical smear, an Evalyn Brush self-test by following the enclosed instructions. After self-sampling, a trained physician obtained a regular cervical smear suspended in ThinPrep medium. The quality of the regular cervical smear will not be influenced by self-sampling with the Evalyn Brush.

**Intervention**

All women are asked to self-collect a cervicovaginal sample with the Evalyn Brush for determination of HPV before the regular cervical smear.

**Study burden and risks**

All participating women should self-collect one additional cervicovaginal self-sample. The risk and burden of the participating women is negligible. Performing a vaginal smear themselves implies no danger for their own health whatsoever. After the examination, all participating women are requested to fill out a short self-administered questionnaire, containing questions on acceptability of using the self-test.

# 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

Women invited by the national screening program for cervical cancer.
Signed informed consent.
Age 30-60 years.
Mentally capable to understand and comprehend the study and its implications.

## Exclusion criteria

Women with mental impairment.
No signed informed consent.
Age < 30 or >60 years.
No sufficient knowledge of the Dutch language to understand the implications of the study, and to answer the questionnaire.

# Study design

## Design

**Study type:** Interventional

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|---|---|
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Prevention |

## Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 11-04-2013 |
| Enrollment: | 2000 |
| Type: | Actual |

### Medical products/devices used

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|---|---|
| Generic name: | self-sampling device |
| Registration: | Yes - CE intended use |

## Ethics review

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| Approved WMO Date: | 12-10-2012 |
| Application type: | First submission |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |

## 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 | NL37385.091.11 |