# Protection by Offering HPV Testing on self-sampled Cervicovaginal specimens Trial.

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|---|---|
| **Ethische beoordeling** | Positief advies |
| **Status** | Werving gestart |
| **Type aandoening** | - |
| **Onderzoekstype** | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON25689

**Bron**
Nationaal Trial Register

**Verkorte titel**
PROHTECT

**Aandoening**

Cervical Intraepithelial Neoplasia (CIN)
Cervical cancer (CxCa)

### Ondersteuning

**Primaire sponsor:** VU University Medical Center, Department of Pathology, Amsterdam, The Netherlands;
IKA (Comprehensive Cancer Center Amsterdam);
RIVM (National Institute of Public Health and Environmental Protection)

**Overige ondersteuning:** VU University Medical Center, Department of Pathology
IKA (Comprehensive Cancer Center Amsterdam)
RIVM (National Institute of Public Health and Environmental Protection)

## Onderzoeksproduct en/of interventie

## Uitkomstmaten

### Primaire uitkomstmaten

The primary outcome measure is the change in compliance rate, i.e., the increase in attendance rate of the cervical screening program after a second recall by using self-sampling material for hrHPV testing, compared to a control group that will receive a second recall for cytological testing (similar to the conventional first recall).

# Toelichting onderzoek

### Achtergrond van het onderzoek

After the introduction of cervical screening programs, cervical cancer incidence decreased impressively. Prevention of uterine cervical cancer is possible due to relatively slowly progressing premalignant lesions, i.e. the mean duration for development of cervical cancer is 13-15 years, that can be detected by cervical cytology or hrHPV-testing, and can be treated effectively. A major problem with current cervical screening programs, however, is that the compliance rate is subject to improvement. Even in well organized invitational programs by the National health authorities, attendance rates reach 63-65% with an additional 7 or 8% of 'passive response' or 'opportunistic screened' women. Almost 25%-30% of the invited women remained unprotected because they do not respond to the general screening invitation (these women are referred to as 'non-responders'). Most importantly, this fraction of unprotected women is responsible for 40-50% of all detected carcinomas.
Our pilot study (Bais et al.) has shown that offering a user-friendly self-sampling method for collecting cell material at home enabled the recruitment of about one-third of these women, who are otherwise unwilling or unable to submit to cytological screening, into the screening program. Consequently, a significant number of premalignant lesions were found. In this PROHTECT trial, we extend the evaluation of offering sampling at home with accompanied high-risk human papillomavirus (hrHPV) testing to the region North Holland and Flevoland in the Netherlands targeting 45.000 non-responders, aiming to reveal:
1)the effect on the attendance rate in the cervical screening program.
2)the non-responder characteristics (i.e., clinical features: percentage of hrHPV positivity and percentage of high grade CIN lesions or worse (>=CIN2-3) found) in comparison to women participating in the conventional screening program.
3)the cost-effectiveness of offering self-sampling in the nation-wide screening program

### Doel van het onderzoek

The main aims of the PROHTECT trial are to find out whether the compliance rate of the cervical screening programme can be improved by offering a self-sampling method for

collecting cervicovaginal cell material at home for HPV testing, and consequently the (cost-)effectiveness of screening will be enhanced due to increased detection of high grade CIN lesions or worse (>=CIN2-3) ?

**Onderzoeksproduct en/of interventie**

In the PROHTECT trial, the effect of the addition of offering self-sampling at home to women who are not responding to the invitation of the regular cervical screening program as well as a first recall, onto the participation rate is evaluated in a randomized controlled trial design. During the trial, participants will receive either a second recall for the regular screening (control group), or receive a kit for self-sampling of a cervicovaginal specimen at home and subsequent referral recommendations based on the presence or absence of hrHPV in the self-taken specimen (intervention group, hrHPV test results disclosed).

# Contactpersonen

## Publiek

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## Wetenschappelijk

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# Deelname eisen

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Women invited for the cervical cancer screening program (ages 30-60 years), but who are not responding to their invitation as well as their recall (3 months after);
2. Residing in the region covered by district health authorities of North Holland and Flevoland

(in the Netherlands).

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Not called for screening, i.e., ages under 30 years, or over 60 years;
2. Actively responded to the invitation or first recall of the cervical screening program by undergoing a cervical smear at the general practitioner;
3. Living outside the region covered by district health authorities of North Holland and Flevoland;
4. Under follow-up by gynaecologist for previous non-normal cytology, i.e., abnormal cytology and/or CIN3 lesion or worse less than 2 years before inclusion;
5. Current pregnancy;
6. Status after extirpation of the uterus or amputation of the portio.

## Onderzoeksopzet

### Opzet

| | |
|---|---|
| Type: | Interventie onderzoek |
| Onderzoeksmodel: | Parallel |
| Blindering: | Open / niet geblindeerd |
| Controle: | Actieve controle groep |

### Deelname

Nederland

| | |
|---|---|
| Status: | Werving gestart |
| (Verwachte) startdatum: | 01-10-2006 |
| Aantal proefpersonen: | 45000 |
| Type: | Verwachte startdatum |

## Ethische beoordeling

Positief advies

| | |
|---|---|
| Datum: | 11-10-2006 |
| Soort: | Eerste indiening |

# Registraties

## Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

| Register | ID |
|---|---|
| NTR-new | NL781 |
| NTR-old | NTR792 |
| Ander register | : 2006/01WBO |
| ISRCTN | ISRCTN45527158 |

# Resultaten

**Samenvatting resultaten**
Brink et al. J Clin Microbiol. 2006; 44:2518-23.
Bais et al. Int. J. Cancer submitted