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# PRotection by Offering Human papillomavirus Testing on sElf-sampled Cervicovaginal specimens Trial

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 28/12/2006 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 28/12/2006 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 06/01/2021 | Cancer | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**Protocol serial number**
2006/01WBO

## Study information

**Scientific Title**

PRotection by Offering Human papillomavirus Testing on sElf-sampled Cervicovaginal specimens Trial

## Acronym
PROHTECT

## Study objectives
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 Human PapillomaVirus (HPV) testing, and consequently the (cost)-effectiveness of screening will be enhanced due to increased detection of high grade Cervical Intraepithelial Neoplasia (CIN) lesions or worse (more than or equal to CIN grade two to three)?

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
The PROHTECT trial has been approved by the Dutch Ministry of Health, Welfare and Sports (reference number: 2006/01WBO), date of approval: 11/05/2006. In addition, the Ethics Board of the VU University Medical Center has approved the study.

## Study design
Randomised controlled parallel-group trial

## Primary study design
Interventional

## Study type(s)
Screening

## Health condition(s) or problem(s) studied
Cervical Intraepithelial Neoplasia (CIN), cervix cancer, uterus

## Interventions
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 randomised 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 high-risk Human PapillomaVirus (hrHPV) in the self-taken specimen (intervention group, hrHPV test results disclosed).

## Intervention Type
Other

## Phase
Not Specified

## Primary outcome(s)

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).

### Key secondary outcome(s))
The secondary outcome measures include:
1. The women characteristics, i.e., the prevalence of HPV and the number of detected high-grade CIN lesions for compliance of referral and treatment among non-responder women compared to women participating in the conventional screening program.
2. Evaluation of the cost-effectiveness of self-sampling when offered in the nation-wide screening program, i.e., counter valuation of the effects on costs versus improved detection rate of premalignant lesions.

### Completion date
01/03/2009

## Eligibility

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

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
Female

### Total final enrolment
28073

### Key exclusion criteria
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 CIN three lesion or worse less than two years before inclusion
5. Current pregnancy
6. Status after extirpation of the uterus or amputation of the portio

**Date of first enrolment**
01/10/2006

**Date of final enrolment**
01/03/2009

# Locations

**Countries of recruitment**
Netherlands

**Study participating centre**
**VU University Medical Center**
Amsterdam
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# Sponsor information

**Organisation**
VU University Medical Center

**ROR**
https://ror.org/00q6h8f30

# Funder(s)

**Funder type**
Hospital/treatment centre

**Funder Name**
Comprehensive Cancer Centre (Integraal Kankercentrum) (The Netherlands) 2. VU University Medical Center (The Netherlands) 3. National Institute of Public Health and Environmental Protection (RIVM) (The Netherlands)

# 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? |
|---|---|---|---|---|---|
| Results article | results | 11/03/2010 | 06/01/2021 | Yes | No |
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |