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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

Contact name
Dr D A M Heideman

Contact details
VU University Medical Center
Department of Pathology
PO Box 7057
Amsterdam
Netherlands
1007 MB
-
dam.heideman@vumc.nl

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.

Primary study design
Interventional

Study design
Randomised controlled parallel-group trial

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
Netherlands
1007 MB

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