

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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25689

Source

NTR

Brief title

PROHTECT

Health condition

Cervical Intraepithelial Neoplasia (CIN)
Cervical cancer (CxCa)

Sponsors and support

Primary 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)

Source(s) of monetary or material Support: VU University Medical Center, Department of Pathology
IKA (Comprehensive Cancer Center Amsterdam)
RIVM (National Institute of Public Health and Environmental Protection)

Intervention

Outcome measures

Primary outcome

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).

Secondary outcome

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.

Study description

Background summary

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 (\geq 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

Study objective

The main aims of the PROTECT 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 (\geq CIN2-3) ?

Intervention

In the PROTECT 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).

Contacts

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Eligibility criteria

Inclusion criteria

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).

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 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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-10-2006
Enrollment:	45000
Type:	Anticipated

Ethics review

Positive opinion

Date: 11-10-2006

Application type: First submission

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
NTR-new	NL781
NTR-old	NTR792
Other	: 2006/01WBO
ISRCTN	ISRCTN45527158

Study results

Summary results

Brink et al. J Clin Microbiol. 2006; 44:2518-23.

Bais et al. Int. J. Cancer submitted