Protection by Offering HPV Testing on self-sampled Cervicovaginal specimens Trial 3.

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In the PROHTECT-3 trial, we offer hrHPV testing on self-sampled (cervico-)vaginal specimens obtained by a lavage device. The sensitivity and specificity for high grade CIN and cervical cancer (CIN2+/CIN3+) of two triage strategies of hrHPV positive...

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

Samenvatting

ID

NL-OMON29624

Bron
NTR

Verkorte titel
PROHTECT-3

Aandoening

Cervical intraepithelial neoplasia (CIN), Cervix cancer

Ondersteuning

Primaire sponsor: VU University Medical Center, Department of Pathology, Univerisity Medical Center Nijmegen, Comprehensive Cancer Center (IKA) Amsterdam , National Institute for Public Health and the Environment (RIVM),
Overige ondersteuning: Comprehensive Cancer Centre (Integraal Kankercentrum), VU University Medical Center, Department of Pathology, National Institute of Public Health and Environmental Protection (RIVM), Stichting Achmea Gezondheidszorg

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The number of CIN 2+ and CIN 3+ lesions in both triage strategies.

Toelichting onderzoek

Achtergrond van het onderzoek

In this randomized-controlled trial, 45.000 registered non-attendees in the regions Noord-Holland/ Flevoland/ Utrecht and Gelderland in the period October 2010 untill October 2011 will be enrolled for self-sampling.

Previous PROHTECT trials have shown that offering a user-friendly self-sampling method for collecting (cervico-) vaginal 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 CIN2+/CIN3+ lesions were found.

In this PROHTECT-3 trial, we extend the evaluation of offering sampling to non-attendees by evaluating two triage strategies, i.e., 1) molecular triage by testing for promoter methylation of host genes (cervix care gene panel) directly on the self-sampled lavage specimens, and 2) cytology triage via visiting the general practitioner for a physician-taken cervical smear.

For this purpose, 45,000 non-responders from the year 2007 are enrolled for self-sampling. hrHPV-positive self-sampling responders will be randomized over two triage arms.

We aim to reveal:

1. The effect of triage by molecular testing or regular cytology on the detection of CIN2+/CIN3+;

2. The participation rate of hrHPV positive women in the both triage strategies;

3. the comparison of the cost-effectiveness of both triage strategies.

Doel van het onderzoek

In the PROHTECT-3 trial, we offer hrHPV testing on self-sampled (cervico-)vaginal specimens obtained by a lavage device. The sensitivity and specificity for high grade CIN and cervical cancer (CIN2+/CIN3+) of two triage strategies of hrHPV positive women will be compared: 1. triage by cytology (ie., referral to a GP for a physician-taken cervical smear); 2. molecular triage by promotor methylation analysis of host genes directly on the self-sampled specimen.

The hypothesis is that molecular triage is at least as good as cytology for the detection of CIN2+/CIN3+ in women with a hrHPV-positive self-sample.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

This randomized-controlled trial is coordinated by the VU University medical center (VUmc) and performed in collaboration with UMCN, the screening organizations Midden-West and Oost and RIVM. In the regions Noord-Holland/ Flevoland/ Utrecht and Gelderland, non-attendees of the regular screening programme will be invited to participate to self-sampling. Based on earlier trials, we expect about 30 percent of these women will respond by sending a self sampled specimen for hrHPV testing, of whom 10 percent will be hrHPV positive (Gök, 2010). Randomization of these hrHPV positive women over two triage arms is performed to determine whether triage by molecular testing for promoter methylation of host genes, i.e., the cervix care gene panel, directly on the self-sampled lavage specimens is at least as effective to detect CIN2+/CIN3+ as cytology via a physician-taken smear.
The trial is powered that triage by the cervix care gene panel is non-inferior to triage by cytology via a physician-taken smear for the detection of CIN2+/CIN3+. We determined that the yield of CIN2+/CIN3+ should be not less than 80% of that of cytology. For a non-inferiority score test, the null hypothesis was therefore set at a yield of 0.80 and the alternative hypothesis at a yield of > 0.80. To achieve power of 80% (significance level 5%, single sided) under the aforementioned assumptions (a participation rate of 30% and a hrHPV positivity rate of 10%) a sample size of 1350 hrHPV positive women is sufficient. To achieve this number of hrHPV positive women, 45.000 women will receive an invitation for self-sampling. Data are analyzed with intention to treat.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Women invited for the cervical cancer screening program in 2007 (ages 30-60 years), who did not respond to an initial invitation and a recall after 3-6 months;

2. Women should reside in the regions covered by district health authorities of Noord-Holland, Flevoland, Utrecht and Gelderland (in the Netherlands).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Not in the population based screening program, i.e. ages under 30 years, or over 60 years;

2. Actively responded to the invitation or recall of the cervical screening program by undergoing a cervical smear at the general practitioner;

3. Under follow-up by gynaecologist for previous abnormal cytology, and/or CIN3 lesion or worse less than 2 years before inclusion;

4. Current pregnancy;

5. Status after hysterectomy or amputation of the portio.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-10-2010
Aantal proefpersonen:	45000
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	17-11-2010
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	NL2489
NTR-old	NTR2606
Ander register	WBO : 2010/04
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

Bais et al. Int. J. Cancer 2007; 120(7):1505-1510.
Gok et al. BMJ 2010; 340:1040.
Gok et al. Int. J. Cancer 2011; Apr 2011.