IMPROVE-study

Gepubliceerd: 13-03-2015 Laatst bijgewerkt: 18-08-2022

In the IMPROVE-study, the clinical performance in terms of clinical sensitivity and clinical specificity for high-grade CIN lesions and cervical cancer (CIN2+/CIN3+) of primary HPV screening via two different sampling methods will be compared: 1....

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

Samenvatting

ID

NL-OMON28209

Bron
NTR

Verkorte titel
IMPROVE

Aandoening

Cervical Intraepithelial Neoplasia (CIN), Cervical cancer

Ondersteuning

Primaire sponsor: VU University Medical Center, Department of Pathology
Erasmus Medical Center, Department of Pathology
Radboud University Medical Center, Department of Gynaecology
National Institute for Public Health and the Environment (RIVM)
Overige ondersteuning: National Institute of Public Health and the Environment (RIVM)
COHEAHR (Comparing health services internventions for the prevention of HPV-related cancer)
VU University Medical Center, Department of Pathology

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The number of CIN2+ and CIN3+ lesions in both study arms

Toelichting onderzoek

Achtergrond van het onderzoek

To evaluate whether clinician-based cervical sampling for HPV testing can be replaced by self-sampling in primary screening, we will perform a randomized pilot implementation trial of self-sampling in primary cervical screening setting. In the intervention (i.e. self-sampling) arm, women are invited for self-collection of (cervico-)vaginal material at home, whereas in the control (i.e. clinician-based sampling) arm women are invited to visit their general practitioner for a cervical (LBC) sample. In both arms, women with hrHPV DNA-positive test results are further triaged with cytology. To enhance the power of the design for assessing the relative sensitivity of self-sample-based HPV testing, women positive for HPV self-sampling (intervention arm) will also be tested by an clinician-based HPV test 2-4 weeks later, and women positive for HPV on a clinician-based sample (control arm) will also be asked to perform HPV self-sampling 2-4 weeks later. This type of design is a randomized paired screen-positive design and has been put forward by Alonzo and Kittelson (2006). In this trial, it will be determined whether HPV self-sampling is not inferior to HPV testing on a clinician-based sample in terms of detection of CIN3+ and CIN2+. To assess non-inferiority of HPV self-sampling in comparison with a HPV test on a clinician-based sample, 30,000 women will be invited for study enrolment.

Doel van het onderzoek

In the IMPROVE-study, the clinical performance in terms of clinical sensitivity and clinical specificity for high-grade CIN lesions and cervical cancer (CIN2+/CIN3+) of primary HPV screening via two different sampling methods will be compared: 1. self-sampling (i.e. by women themselves), and 2. clinician-based sampling (i.e. cervical smear taken by GP). The hypothesis is that HPV self-sampling is at least as good as HPV testing on a clinician-based sample for the detection of CIN2+/CIN3+ in women attending the national cervical screening program.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

Women who are eligible for the national cervical screening program receive an invitation to participate in this study. When women return a signed informed consent form, they will be randomized between self-sampling (intervention arm) and a clinician-based sample (control arm). Both samples will be tested for the presence of high-risk Human Papillomavirus (hrHPV) DNA by a validated assay.

Women whose samples (self-sample or clinician-based sample) test hrHPV DNA negative are referred to the next screening round after 5 years. Women whose sample test positive for hrHPV DNA will undergo cytology triage (based on the new screening program starting 2016). For women in the intervention arm, cytology triage will be done on a newly obtained clinician-based smear taken within a month. Accordingly, these women are asked to visit the GP. For women in the control arm, the remaining material of the cervical sample can be used for (reflex)cytology testing.

Additionally, all hrHPV-DNA positive women (both arms) will be asked to perform similar sampling as done in the cross arm 2-4 weeks after the first analysis, i.e., women in the intervention arm will go to their GP for a clinician-based sample (this is already needed to perform cytology triage) that will be tested for hrHPV DNA; women in the control arm will be asked to perform additional self-sampling for hrHPV DNA testing. This cross-testing is performed to see if individual HPV results match between the self-sample and the clinician-based sample.
In both arms, if baseline cytology triage shows abnormalities (¡ÝBMD cytology), women will be referred for colposcopy. If baseline cytology triage shows no abnormalities (normal cytology), women will be invited for repeat cytology testing at 6 months. Again, if this cytology test shows abnormalities (¡ÝBMD cytology), women will be referred for colposcopy.

If necessary, women will be treated according to national guidelines. If 6-month cytology shows no abnormalities (normal cytology), women will receive a new invitation for screening in the next screening round (approx. after five years).

Contactpersonen

Publiek

VU medisch centrum; Department of Pathology

N.J. Polman
Boelelaan 1117

Amsterdam 1081 HV
The Netherlands

+31 20 444 01 02

Wetenschappelijk

VU medisch centrum; Department of Pathology

N.J. Polman
Boelelaan 1117

Amsterdam 1081 HV
The Netherlands
+31 20 444 01 02

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Women invited for the national screening program in 2015 (ages 30-60 years)

2. Women should reside in the regions covered by district health authorities of Noord-Holland, Flevoland, Utrecht, Zuid-Holland, Zeeland, Gelderland en Overijssel (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. Cervical smear in the past 12 months or under follow-up/treatment by gynaecologist

3. Current pregnancy

4. Hysterectomy, incl. cervix

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	16-03-2015
Aantal proefpersonen:	12000
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	13-03-2015
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	NL4806

Register	ID
NTR-old	NTR5078
Ander register	: WBO 2014/32

Resultaten

Samenvatting resultaten
Gök et al. BMJ 2010
Gök et al. Int J Cancer 2011
Verhoef et al. Lancet Oncol 2014
Bosgraaf et al. Int J Cancer 2014
