HrHPV in the population research on cervical cancer.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28695

Source
NTR

Brief title
POBASCAM

Health condition

Cervical intraepithelial neoplasia and cervical cancer.
Due to the low prevalence of invasive cervical cancer in the Netherlands, and the aim of cervical screening to prevent the occurrence of and death caused by to cervical cancer, we evaluate the prevalence of a surrogate marker for cervical cancer incidence, namely the immediate precursor lesion of cervical cancer cervical intra-epithelial neoplasia grade 3.

Sponsors and support

Primary sponsor: - Department of Pathology, VU University Medical Center
- Department of Pathology, Spaarne Ziekenhuis, Hoofddorp
- Leiden Cytology and Pathology Laboratory, Leiden
- Stichting PA Laboratorium Kennemerland, Haarlem
Source(s) of monetary or material Support: ZonMW, grant number 30-0522

Intervention

Outcome measures

Primary outcome

The primary outcome measure of POBASCAM trial is the occurrence of histologically confirmed cervical intra-epithelial neoplasia grade 3 (CIN3) lesions or (micro-) invasive carcinoma of the cervix found during the time span from intake up to and including the next screening round, i.e., in 5 years.
Since women with normal cytology at the next screening round will not be referred for colposcopically-directed biopsies and therefore will not have a histological endpoint, it will be assumed that no precursor lesions of cervical cancer are present.
This policy complies with regular cervical screening in The Netherlands.

Secondary outcome

As a secondary outcome measure, histologically confirmed cervical intra-epithelial neoplasia grade 2 will also be investigated, since current guidelines recommend ablative treatment for these lesions as well.
Other secondary parameters obtained include progression and regression of cytology diagnoses, clearance and acquisition of hrHPV infections and the number of referrals for colposcopically-directed biopsies.

Study description

Background summary

After the introduction of cervical screening programmes, cervical cancer incidence decreased impressively. However, cytological screening has a both a low sensitivity and a low specificity. To improve the performance of cervical screening, we evaluate the addition of high-risk human papillomavirus (hrHPV) testing to the nationwide cervical screening programme in the Population Based Screening Amsterdam (POBASCAM) trial.
- The main aims of the POBASCAM trial are to find out whether the efficacy and cost-effectiveness of the cervical screening programme can be improved by increasing the screening interval for women with normal cytology and a negative hrHPV test, and by referring women with BMD and a negative hrHPV test back to the next screening round, without increasing the risk of missing CIN3 lesions or cervical cancer.
- Participants are randomized into two study groups, a control group and an intervention group. The participants randomized to the control group receive cytology results only and regular repeat and referral recommendations are provided. The participants randomized to the intervention group receive recommendations based on both cytology and hrHPV test results and participants positive for hrHPV will be followed more intensively than current Dutch screening guidelines recommend.
- The outcome measure of the trial is the detection of histologically confirmed precursor lesions of cervical cancer and invasive cervical cancer in each study group up to and

including the next screening round after five years.
- The parameters obtained in the POBASCAM trial will be used in modeling studies, including a cost-effectiveness analysis.
- The follow-up will be completed when the women have participated in the next screening round, i.e., five years after enrolment in the study.
The POBASCAM trial has been extended with approximately 10,000 participants using the same repeat and referral algorithm.

Study objective

The main aims of the POBASCAM trial are to find out whether the efficacy and cost-effectiveness of the cervical screening programme can be improved by increasing the screening interval for women with normal cytology and a negative hrHPV test, and by referring women with mild cytological abnormalities and a negative hrHPV test back to the next screening round, without increasing the risk of missing CIN3 lesions or cervical cancer.

Study design

N/A

Intervention

In the POBASCAM trial, the addition of a high-risk human papillomavirus (hrHPV) test to the regular cervical screening programme to improve detection of precursor lesions of cervical cancer is evaluated in a randomized trial design.
During the trial, participants will receive either the regular test results and regular repeat and referral recommendations (control group, hrHPV test results blinded to participants, treating clinicians and study personnel) or participants will receive modified repeat and referral recommendations based on the presence or absence of hrHPV in the cervical smear (intervention group, hrHPV test results disclosed).

Contacts

Public
VU University Medical Center, Department of Pathology,
De Boelelaan 1117
N.W.J. Bulkmans
De Boelelaan 1117
Amsterdam 1081 VH
The Netherlands
+31 (0)20 4440102
Scientific
VU University Medical Center, Department of Pathology,
De Boelelaan 1117

N.W.J. Bulkmans
De Boelelaan 1117
Amsterdam 1081 VH
The Netherlands
+31 (0)20 4440102

Eligibility criteria

Inclusion criteria

1. Women invited for the cervical cancer screening program (ages 30-60 years);

2. Residing in either the region covered by district health authority Amstelland-de Meerlanden and Zuid-Kennemerland.

Exclusion criteria

1. Not called for screening, i.e., ages under 30 years, or over 60 years;

2. Follow-up of previous non-normal cytology within the current screening round of the program, i.e., abnormal cytology or CIN lesions less than 2 years before inclusion;

3. Status after extirpation of the uterus or amputation of the portio.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-1999
Enrollment:	44102
Type:	Actual

Ethics review

Positive opinion Date:	05-09-2005
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	NL181
NTR-old	NTR218
Other	: 1998/04WBO
ISRCTN	ISRCTN20781131

Study results

Summary results
- NWJ Bulkmans, L Rozendaal, PJF Snijders, FJ Voorhorst, AJP Boeke, GRJ Zandwijken, FJ van Kemenade, RHM Verheijen, K v Groningen, ME Boon, HJF Keuning, M van Ballegooijen, AJC van den Brule, CJLM Meijer. POBASCAM, a population-based randomised controlled trial for

implementation of high-risk HPV testing in cervical screening; Design, methods and baseline data of 44,102 women. International Journal of Cancer 2004; 110 (1): 94-101. DOI 10.1002/ijc.20076
- NWJ Bulkmans, MCG Bleeker, J Berkhof, FJ Voorhorst, PJF Snijders, CJLM Meijer. Prevalence of types 16 and 33 is increased in high-risk human papillomavirus positive women with cervical intraepithelial neoplasia grade 2 or worse. International Journal of Cancer 2005; 117 (2): 177-181. DOI: 10.1002/ijc.21210