

High-risk human papillomavirus (HrHPV) in the population research on cervical cancer

Submission date 20/12/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 20/12/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 31/10/2022	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
1998/04WBO; NTR218

Study information

Scientific Title
High-risk human papillomavirus (HrHPV) in the population research on cervical cancer: a randomised clinical trial

Acronym

POBASCAM

Study objectives

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 high-risk human papillomavirus (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 cervical intraepithelial neoplasia 3 (CIN3) lesions or cervical cancer.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local medical ethics committee

Study design

Multicentre, randomised, triple blinded, active controlled, parallel group trial.

Primary study design

Interventional

Study type(s)

Screening

Health condition(s) or problem(s) studied

Cervical intraepithelial neoplasia

Interventions

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 randomised 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).

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

The primary outcome measure of POBASCAM trial is the occurrence of histologically confirmed 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 five 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.

Key secondary outcome(s)

As a secondary outcome measure, histologically confirmed cervical intraepithelial 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.

Completion date

01/09/2007

Eligibility

Key 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

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

1. Not called for screening, ie 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 two years before inclusion
3. Status after extirpation of the uterus or amputation of the portio

Date of first enrolment

01/01/1999

Date of final enrolment

01/09/2007

Locations

Countries of recruitment

Netherlands

Study participating centre
VU University Medical Center,
Amsterdam
Netherlands
1081 VH

Sponsor information

Organisation

Vrije University Medical Centre (VUMC) (The Netherlands)

ROR

<https://ror.org/00q6h8f30>

Funder(s)

Funder type

Research organisation

Funder Name

The Netherlands Organization for Health Research and Development (ZonMw) (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

Not provided at time of registration

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	Association between higher-grade CIN and HPV type	01/11/2005		Yes	No
Results article	Final results	01/01/2012		Yes	No
Other publications	Design, methods and baseline data:	20/05/2004		Yes	No
Other publications	5-year follow-up	24/11/2007		Yes	No

Other publications	Post hoc analysis of 14-year follow-up data	15/09/2018		Yes	No
Other publications	Association between cervical precancer risk at 14 years and previous screening results	28/10/2022	31/10/2022	Yes	No