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

Submission date 20/12/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 20/12/2005	**Overall study status** Completed	
Last Edited 31/10/2022	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Screening

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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.

Secondary outcome measures
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.

Overall study start date
01/01/1999

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

Age group
Adult

Sex
Female

Target number of participants
44,102

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)

Sponsor details
Department of Pathology
PO Box 7057
Amsterdam
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1007 MB

Sponsor type
University/education

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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