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Efficacy of addition of high-risk human papillomavirus (hrHPV) testing by Hybrid Capture II to conventional cytological screening for cervical cancer

Submission date
20/12/2005

Recruitment status
No longer recruiting

Registration date
20/12/2005

Overall study status
Completed

Last Edited
19/12/2008

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

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
NTR215; 2002/02WBO

Study information

Scientific Title

Acronym
VUSABOB

Study objectives
1. In this study, we expect to decrease the number of referrals and repeat smears by immediately referring those women who are positive for high-risk human papillomavirus (hrHPV) with mildly abnormal smears for colposcopically-directed biopsies. Thus, for the remaining women with BMD who have tested hrHPV negative, repeat smears will not be necessary.
2. Secondly, we expect to be able to narrowly define a risk group of women within the group with normal cytology, that has an increased risk for the development of high-grade lesions based on the presence of hrHPV in the smear.

The hrHPV negative women with normal smears will be at a decreased risk for the development of high-grade lesions, and for them, the interval between screening smears could be increased (from an interval of 5 years, to an interval of 8 - 10 years).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from local medical ethics committee

Study design
Randomised triple-blinded active controlled parallel group trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Cervical intraepithelial neoplasia

Interventions
In the VUSABOB, the addition of a high-risk human papillomavirus (hrHPV) test, using the commercially available and FDA approved Hybrid Capture II test, to the regular cervical screening programme in order to improve detection of precursor lesions of cervical cancer is evaluated using a cohort study of women whose smears were consecutively screened at a single laboratory in The Netherlands. Within this cohort study, we nested an unblinded trial of women with mildly abnormal screening smears and repeat and referral recommendations were based on the presence or absence of high-risk human papillomavirus.

Secondly, we nested a randomised trial of women with normal cytology whose hrHPV test results were triple blinded to participants, treating clinicians and study personnel, and advised all women with blinded test results to repeat cervical screening at earlier intervals than current screening guidelines in the Netherlands recommend in order to evaluate screening strategies for women with normal cytology and a positive hrHPV test.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
The primary outcome measure of VUSABOB is the occurrence of histologically confirmed cervical intra-epithelial neoplasia grade 3 (CIN3) lesions or (micro-) invasive carcinoma of the cervix found during the follow-up of currently diagnosed abnormalties, i.e., within 2 years. For women whose cytology results either regress to normal (in the unblinded trial of women with mild cytological abnormalities) or who clear an infection with hrHPV without cytological abnormalities (in the blinded trial of women with normal cytology diagnoses), we assume that no precursor lesions of cervical cancer are present. They will not be referred for colposcopically-directed biopsies and therefore will not have a histological endpoint. This policy complies with regular cervical screening in The Netherlands.

Key secondary outcome(s))
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.

Completion date
01/12/2007

Eligibility

Key inclusion criteria
1. Women invited for the cervical cancer screening program (aged 30 - 60 years)
2. General practitioner affiliated with SALTRO laboratory

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key 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 lesion greater than or equal to CIN3 less than 2 years before

inclusion
3. Current pregnancy
4.Status after extirpation of the uterus or amputation of the portio

Date of first enrolment
01/10/2003

Date of final enrolment
01/12/2007

Locations

Countries of recruitment
Netherlands

Study participating centre
SALTRO
Utrecht
Netherlands
3565 CE

Sponsor information

Organisation
SALTRO - Doctor Laboratory & Thrombosis Service (The Netherlands)

ROR
https://ror.org/00q6h8f30

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Vrije University Medical Centre (VUMC) (The Netherlands) - Department of Pathology

Funder Name
SALTRO - Doctor Laboratory & Thrombosis Service (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration