

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	<input type="checkbox"/> Prospectively registered
Registration date 20/12/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 19/12/2008	Condition category Cancer	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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 measure

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 abnormalities, 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.

Secondary outcome measures

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.

Overall study start date

01/10/2003

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

Age group

Adult

Sex

Female

Target number of participants

25000

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)

Sponsor details

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Sponsor type

Hospital/treatment centre

Website

<http://www.saltro.nl/default.aspx>

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

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration