

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

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<b>Registration date</b> 20/12/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 19/12/2008	<b>Condition category</b> 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