HPV testing and the long term risk at cervical disease

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Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24787

Bron
NTR

Verkorte titel
N/A

Aandoening

(pre)malignant cervical laesions, Cervical Intraepithelial neoplasia (CIN), Human Papillomavirus (HPV), long term
In Dutch: (pre)maligne afwijkingen cervix,
CIN, Humaan papillomavirus (HPV), lange termijn

Ondersteuning

Primaire sponsor: HUMAVAC (VU University Medical Center)
Overige ondersteuning: HUMAVAC (VU University Medical Center)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Intraepithelial Neoplasia (CIN) 2 or 3 and adenocarcinoma in situ (AIS), diagnosed after a follow up period of up to 18 years after an abnormal cervical smear.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:
In the Netherlands each year approximately 8000 women are treated for a high-grade pre-malignant cervical lesion. The majority of these lesions are detected in the population based cervical cancer screening program, in which exfoliated cells of the cervix are microscopically examined.

A disadvantage of the current (cytological) test is the poor sensitivity (around 60%), leading to false-negative results. Since a persistent infection with human papillomavirus (HPV) is the key causative agent in the development of cervical lesions, women at risk can be identified by a HPV test (GP5+/6+ primer-mediated PCR with enzyme immuno assay read-out). This test has a sensitivity of approximately 90% and a negative predictive value of almost 100% for high-grade pre-malignant lesions measured over a short period of time (up to 2 years). In order to give a well-founded advice how to adjust the screening test for cervical cancer to the HPV test, the predictive value on the long term development of cervical abnormalities has to be known.

Objectives:

Primary objectives:

- Determining the long-term predictive value of a positive HPV test for (pre)malignant cervical disease.

- Determining the long-term protective value of a negative HPV test.

- Determining the long-term protective value of a negative cervical smear test.

Secondary objectives:

- Determining the cumulative incidence of cervical disease in the investigated group.

- Comparison of the long term predictive value of the HPV test to cytology.

- Determining acquisition of HPV infection in women with a previous cytological abnormality.

- Evaluation of the presence of E6/E7 antibodies in women with an abnormal smear history.

- Comparison of the cost-effectiveness of the HPV test to the current situation of cytology.

Study design:
The study is designed as an open prospective longitudinal clinical cohort study.

Study population:
The study population exists of the cohort of women, previously described in the Lancet in a study by Nobbenhuis et al. in 1999. This cohort of 353 women was referred for of an abnormal smear to the colposcopic outpatient clinic of the VU University Medical Center in Amsterdam between June 1990 and December 1992 and had a median follow-up time of 33 months. The aim was to find out whether the presence of HPV was associated with progression and absence of HPV with regression of cytological abnormalities. The study cohort consists of these 353 women of whom the long term follow-up up to 18 years will be evaluated.

Study parameters:
The main study parameter is the cumulative number of histological confirmed cases of Cervical Intraepithelial Neoplasia (CIN) 2 or 3 or adenocarcinoma in situ (AIS), diagnosed in a follow-up up to 18 years. The secondary study parameters include the results of cervical cytology, the presence of hrHPV, hrHPV typing, the results of the questionnaire and the histology results of all endocervix samples and biopsies taken. All study parameters will result in an evaluation of the protective value of a negative HPV test compared to the value of a negative cytological smear.

Risks and burden for patients:
Risks and burden are linked to protocol procedures, such as cervical sampling, blood withdrawal and, if applicable, colposcopy. Although these are routine procedurese, carried out by medical qualified personnel, they may cause side effects or discomfort to the subject. However, it is expected that these procedures will generally be well tolerated.

Onderzoeksopzet

All outcomes will be obtained in the first study visit. Only in case of a positive HPV type and/or a abnormal cervical smear a colposcopy will take place and will histology results of endocervix and biopsies be known in a second visit.

Onderzoeksproduct en/of interventie

All women are invited to the outpatient clinic, where a blood sample and a cervical smear for cytology and HPV testing will be taken.

If the HPV test is HPV positive or if cytology is abnormal a second visit will be planned to perform a colposcopy. In case of high-grade disease the current Dutch guidelines for treatment will be followed.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

All subjects must satisfy the following criteria at study entry:

1. Previous participation in the following study: 'Relation of human papillomavirus status to cervical lesions and consequences for cervical screening: A prospective study'.

2. Written informed consent prior to enrolment.

3. Sufficient knowledge of the Dutch or English language.

4. The intention to comply with the requirements of the protocol.

Belangrijkste redenen om niet deel te kunnen nemen

(Exclusiecriteria)

1. Pregnancy.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-10-2008
Aantal proefpersonen:	353
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1410
NTR-old	NTR1470
Ander register	: CCA/V-ICI 08/61
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A