a retrospective longitudinal clinical cohort study to investigate HPV testing post-treatment and the risk of recurrence of (cervical) disease on the long term.

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The primary objective is to determine the positive and negative predictive value of an hrHPV test after treatment for the development of recurrent (cervical) disease on the long term.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Reproductive neoplasms male malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON32424

Source
ToetsingOnline

Brief title
HPV test post-treatment and follow-up

Condition

- Reproductive neoplasms male malignant and unspecified
- Cervix disorders (excl infections and inflammations)

Synonym
cervical cancer, CIN

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cervical Intraepithelial Neoplasia(CIN), Humane papillomavirus (HPV), long term, Recurrence

Outcome measures

Primary outcome

The main study parameter is the number of histological confirmed cases of high-grade disease (including CIN 2/3, AIS and VaIN 2/3), diagnosed after a follow-up period of up to 18 years after treatment for a high-grade cervical lesion (CIN 2/3).

Secondary outcome

The secondary study parameters include:

- the results of cervical cytology
- the presence of hrHPV
- the type of hrHPV
- the results of the questionnaire (including sexual behavior, smoking and previous vaccination)
- the histological results of all endocervical samples and biopsies taken in the study and revision and additional hrHPV testing of all "interval" lesions in between the index study and the current study.

Study description

Background summary

In the Netherlands, each year over 5000 women are treated for a high-grade premalignant cervical lesion (Cervical Intraepithelial Neoplasia * CIN). Since a persistent infection with the human papillomavirus (HPV) is the key causative agent in the carcinogenesis, the presence of this virus can be demonstrated by a HPV test (GP5+/6+ PCR enzyme immuno assay). Despite treatment, the overall prevalence for recurrent disease is stated between 5 and 30 percent, with the majority occurring in the first two years after initial treatment. Even after 20 years however, the risk to develop a recurrent lesion is still significantly increased. Furthermore, women who have been treated for prior cervical cancer have a high relative, although low absolute, risk of being diagnosed with anal and/ or vaginal cancer.
If the hrHPV is cleared after treatment, this has a negative predictive value of almost 100 percent. However, hrHPV persistence is highly associated with the recurrence of a premalignant lesion within two years. Only few studies have investigated the predictive value of the hrHPV test on the development of premalignant genital lesions on the long term. More insight into this relation may lead to more efficient strategies to identify the women at risk for recurrent high-grade (cervical) disease.

Study objective

The primary objective is to determine the positive and negative predictive value of an hrHPV test after treatment for the development of recurrent (cervical) disease on the long term.

Study design

The study is designed as a retrospective longitudinal clinical cohort study in which we investigate the chance of the development of recurrent disease on the long term of the cohorts described in Study Population.
All these women will be contacted to give a brief overview of the study and to ask in they want to receive information over our new study. If so, a PIF will be send. After approximately two weeks an appointment at the research consulting hour at the outpatient clinic of one of the participating hospitals; the VU University Medical Center in Amsterdam, the Erasmus University Medical Center in Rotterdam or the Reinier de Graaf hospital in Voorburg, is made for subjects who are willing to participate.
In general, the subject will visit the outpatient clinic only once. In this visit the following acts will be performed:
- Check inclusion and exclusion criteria.
- Obtain written informed consent and assign study number
- Collect gynaecological history, and complete behavioral questionnaire
- Collect a cervical (vaginal) sample for hrHPV testing as well as for cytological evaluation.

- Make an appointment to discuss the test results.

If women experience a visit to the outpatient clinic as a hugh problem, it is possible to participate in the study by self-sampling. In that case women are asked to perform a self-sampling at home and send the sample by mail for HPV testing and cytological examination.

In case the result of an abnormal cervical smear or a positive hrHPV test, a follow-up visit will be scheduled for additional colposcopy.If a high-grade pre-malignant lesion is diagnosed during colposcopy, the subject will be treated according to the current Dutch guidelines.

Study burden and risks

The possible benifit for the participating subject may be the earlier detection of a cervical lesion in comparison to those subjects who only participate in the population based screening program.

Risks and burden are linked to protocol procedures, such as cervical sampling and, if applicable, colposcopy. Although these are routine procedures, 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.

Contacts

Public
Vrije Universiteit Medisch Centrum

Postbus 7057
1007 MB Amsterdam
Nederland
Scientific
Vrije Universiteit Medisch Centrum

Postbus 7057
1007 MB Amsterdam
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

All subjects must satisfy the following criteria at study entry:
- Previous participation in one of the studies, described in section study population
- Written informed consent prior to enrolment.
- Sufficient knowledge of the Dutch or English language.
- The intention to comply with the requirements of the protocol.

Exclusion criteria

Pregnancy (or delivered within three months)

Study design

Design

Study phase:	4
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-08-2009

Enrollment:	445
Type:	Actual

Ethics review

Approved WMO Date:	18-03-2009
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL25329.029.08