The Prevalence and Genotype of Genital (High-Risk) Human Papillomavirus Infections in Female Renal Transplant Recipients

Published: 07-10-2011
Last updated: 28-04-2024

To study the (high-risk) HPV-infection prevalence and genotype in a cohort of female renal transplant recipients in order to offer adequate follow up for the patients who are infected with high-risk HPV.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Female reproductive tract infections and inflammations
Study type	Observational invasive

Summary

ID

NL-OMON35840

Source
ToetsingOnline

Brief title
(hr)HPV-infection prevalence and genotype in female RTRs

Condition

- Female reproductive tract infections and inflammations

Synonym
Cervico-vaginal HPV infection, Human papillomavirus infection of the cervix

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: (Pre)malignancy, Human papillomavirus, Renal transplantation, Self-sampling

Outcome measures

Primary outcome

The main study parameters are the prevalence of HPV infections and the distribution of different HPV genotypes in our immunocompromised cohort.

Secondary outcome

Secondary endpoints are the prevalence of abnormal PAP smears and of cervical pathology as diagnosed by gynaecological examination and colposcopy.

Other study parameters:

Population characteristics (sociodemographic features, medical data and information regarding sexual behaviour) and experiences of the self-sampling will be evaluated as well. Moreover, we will compare sociodemographic and medical data of the non-responders (i.e. age, marital status and duration of immunosuppression which will retrospectively be collected from the medical charts of these patients) with corresponding data of the responders.

Study description

Background summary

Each year about 800 renal transplantations are performed in the Netherlands. The current immunosuppressive strategies have led to a 1-year patient and graft survival of more than 90%. This high survival rate urges to pay increasing attention to the development of (pre)malignancies as a long-term side effect of

immunosuppressive medication. Renal transplant recipients have a significantly increased risk to develop malignancies of the lower anogenital tract, e.g. cervix, vulva and anus. These malignancies are among the most common malignancies in renal transplant recipients. The carcinogenic role of human papillomavirus (HPV) in cancer of the lower genital tract is clear, but it is largely unknown whether the prevalence and genotypes of HPV change during immunosuppression. The results of this project will provide useful information with respect to HPV infections that could also be applicable to other immunocompromised patients. Moreover, the results of this study will enable us to gain more evidence for the usefulness of HPV vaccination for patients on the waiting list for transplantation in order to prevent the development of lower genital tract malignancy in immunocompromised patients.

Study objective

To study the (high-risk) HPV-infection prevalence and genotype in a cohort of female renal transplant recipients in order to offer adequate follow up for the patients who are infected with high-risk HPV.

Study design

Observational cohort study

Study burden and risks

Patients are asked to fill in one questionnaire and to perform one cervico-vaginal self sample in the privacy at home. In case of being high-risk HPV positive, the patient will be advised to visit the outpatient clinic of Obstetrics & Gynaecology of the RUNMC for a PAP smear. In case of an abnormal PAP smear, the patient will be advised to have further gynaecological examination and colposcopy.
There are no risks to self-sampling when performed as explained in the supplied instruction forms.

Contacts

Public
Universitair Medisch Centrum Sint Radboud

Postbus 9101
6500 HB Nijmegen
NL
Scientific
Universitair Medisch Centrum Sint Radboud

Postbus 9101
6500 HB Nijmegen
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

• Female sex
• Received a renal transplantation at the RUNMC in the period 1968 - 2008
• Age >= 18 years at start of the study

Exclusion criteria

• Patients not willing to sign and/or return the informed consent form
• Patient is pregnant, or within a period of 3 months after delivery
• Patient is within a period of 3 months after miscarriage

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	29-02-2012
Enrollment:	500
Type:	Actual

Ethics review

Approved WMO

Date:	07-10-2011
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL36012.091.11