HPV infections of the penis among men who have sex with men

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Viral infectious disorders
Study type	Observational non invasive

Summary

ID

NL-OMON40642

Source
ToetsingOnline

Brief title
HPV Penis Study

Condition

- Viral infectious disorders
- Male reproductive tract infections and inflammations
- Skin and subcutaneous tissue disorders NEC

Synonym
"HPV induced flat penile lesions", "presence of HPV on the skin of the penis"

Research involving
Human

Sponsors and support

Primary sponsor: GGD Amsterdam
Source(s) of monetary or material Support: interne onderzoeksfinanciering GGD Amsterdam

Intervention

Keyword: HIV, HPV, lesions, penile skin

Outcome measures

Primary outcome

Presence, quantity and size of flat penile lesions

Secondary outcome

HPV detection in swab of penile shaft/outer foreskin

HPV detection in swab of penile glans/corona

HPV viral load

Study description

Background summary

Worldwide, human papillomavirus (HPV) is the most common sexually transmitted virus, and can infect epithelial cells of anogenital skin and mucosa. Over 40 different mucosal HPV-types have been identified. Among both sexes, anogenital HPV infections are associated with a wide range of diseases, from benign conditions like anogenital warts, to malignancies like cervical cancer, anal cancer and certain head and neck cancers. Previous studies have shown that certain HPV-types are more likely to cause benign conditions, whereas others are associated with malignant diseases. In most cases, infection with HPV occurs asymptomatic, causing no visible lesions at the anogenital site, and infected individuals are not aware of carrying the viral infection. Using a staining dilution (acetic acid 3%) at the anogenital site can result in acetowhite lesions , and are thought to be responsible for transmission of HPV from one individual to the other. At the penile site, these lesions are referred to as flat penile lesions. It remains unclear if presence, size and quantity of flat penile lesions is related to specific HPV-types and/or health characteristics (such as hiv infection) of the infected individual.

Study objective

This study's major aim is to determine whether a relation can be found between specific penile HPV types and the presence, quantity and size of flat penile lesions. Secondly, other possible determinants, such as HIV status,

circumcision status and sexual behaviour, will be studied for their relationship with presence, quantity and size of flat penile lesions. Finally, we want to determine whether HPV infected people with flat penile lesions have the same HPV viral load as HPV infected people without flat penile lesions.

Study design

We will perform a descriptive clinical study, in which participants will be invited to visit the GGD Amsterdam for a single study visit. During the study visit: 1) a questionnaire on sexual behaviour and health characteristics will be filled in by the participant, 2) two HPV swabs of the penile skin will be collected by a research physician, and 3) the research physician will inspect the penile skin, using a colposcope, before and after applying acetic acid 3% staining dilution, for the presence, quantity and size of flat penile lesions.

Study burden and risks

Study subjects will be asked to pay a visit to the GGD Public Health Center in Amsterdam, which will last for an estimated 45 minutes. During this visit they will fill in a digital questionnaire on sexual behaviour and health characteristics, 2 swabs of the penile skin will be collected by the research physician, and the research physician will inspect the skin of the penis with a colposcope before and after applying a staining dilution (acetic acid 3%). The procedure of HPV swab collection is painless and safe, and the results following swab analysis are of no influence on the subjects well being, need no treatment, or further follow-up. The procedure of skin inspection with colposcope using a staining dilution is safe, painless and is standard practice in the diagnosis of HPV related disease, such as anogenital warts or inspection of the cervix. The staining of the skin is temporary. Inspection of the genital area could result in experiencing feelings of embarrassment or discomfiture. Study subjects will be thoroughly clarified about the study procedures and have sufficient time to decide whether they would feel comfortable in joining the study. There is no patient-doctor relationship or otherwise dependency of the study subject on the research group, that could influence his decision making.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Inclusion criteria for the HPV Penis Study are:
- men who have been previously included in the H2M study
- who visit one of the two recruitment sites, namely "the MSM cohort of the GGD" or "the HIV Outpatient Clinic"
- of whom HPV-results of at least 4 penile swabs are available (collected during participation in the H2M study)

Exclusion criteria

- Participants with wound(s) or ulcer(s) of the penile skin will be excluded from the study.

Study design

Design

Study type: Observational non invasive
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-12-2015
Enrollment:	168
Type:	Actual

Ethics review

Approved WMO

Date:	20-08-2014
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	NL49748.018.14