Presence of Human Papilloma Virus in different antomical sites in men.

Published: 12-06-2007 Last updated: 09-05-2024

Determine the following:1) What is thé main harbouring site of HPV in men ?2) What is the golden standard for male HPV screening ?3) What is the main HPV genotype in men ?4) Is there a HPV genotype specific anotomical site in men?

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON29911

Source ToetsingOnline

Brief title HPV in men.

Condition

- Other condition
- Reproductive and genitourinary neoplasms gender unspecified NEC

Synonym

carriers of Human Papilloma Virus, HPV screening

Health condition

Virale infectie thv het uro-genitaal

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud **Source(s) of monetary or material Support:** Ministerie van OC&W,Rovers Medical Devices B.V., NL - 5347 KV Oss,Rovers Medical Devices B.V.;NL - 5347 KV Oss

Intervention

Keyword: Anatomical sites, Human Papilloma Virus, Men, PCR

Outcome measures

Primary outcome

- 1) What is the main harbouring site for HPV in men?
- 2) What is the golden standard method for male HPV screening?
- 3) Which HPV-genotype is most frequently found in men?
- 4) Is there a HPV genotype specific anotomical site in men?

Secondary outcome

1) Is the HPV-genotype found in men the same genotype as found in the endo-/

ecto cervical lesions of their partner?

(only for group 1, not for the control group)

Study description

Background summary

Human Papilloma Virus (HPV) is a sexually transmitted infection (SOI). Genotypes 6 and 11 causes benign, still bothersome, lesions such as condylomata accuminata. The high-risk-types (16, 18, 31, 45) causes malign lesions in the anogenital region. Within 5 years after starting having sexual intercourse 80% of the people has had an asymptomatic HPV-infection. We can presume that after some time 100% of the sexually active part of the population has been infected with HPV at some point in their life. About HPV and women is known a lot since HPV is a causal co-factor for cervical carcinoma. Since HPV is a SOI, also men are infected. About HPV and men is less known, since the prevalence of HPV-related malignancies in men (penile cancer, anogenital cancer) is much lower then in women. Probably this is due to the histological differences in the epithelial coating of the lower urogenital tract in both genders. Whe don't know yet how and if we have to treat HPV-infected males. Since they can be a longterm carrier of the virus they can re-infect their partner. The usefulness of male HPV-screening is still under discussion, but at the same time this discussion is the relevance of this study. Following problems rise:

1) What is the harbouring site of HPV in men?

2) Are different HPV genotypes found in the different anatomical sites. (e.g.

in females HPV 16 is found in the ectocervix while HPV 18 and 45 are found in the endocervix).

3) As a consequence of 1) what is the golden standard for male HPV screening.

4) Is there a genotype-specific prevalence of HVP in men?

Study objective

Determine the following:

1) What is the main harbouring site of HPV in men?

2) What is the golden standard for male HPV screening ?

3) What is the main HPV genotype in men?

4) Is there a HPV genotype specific anotomical site in men?

Study design

Men with a high-risk-HPV-infection profile and a low-risk-HPV-infection profile (control group) are asked to participate voluntarely.

Men with a CIN-positive partner are put in the high-risk-group. Men who contact us concerning non-HPV-related complaints are put in the low-risk-group.

They are asked to fill in a questionnaire, their medical history is taken, they get a physicale examination. 4 anantomical sites are sampled: anus, glans, corona glandis, meatus urethrae. They are asked to provide a urine- and a sperm sample.

Study burden and risks

None, only an investment of time.

Contacts

Public

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Age between 18 - 50 years old Understanding the investigation and it's consequences Signing the informed consent + Being the partner of an HPV-positive female patient (CIN) (groep 1) + Not being the partner of an female partner with HPV-positive cervical lesion(control gruop)

Exclusion criteria

Younger then 18 years old, older then 50 years old Not being able to understand the investigation

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-12-2006
Enrollment:	50
Туре:	Anticipated

Ethics review

1 14/14/0

Approved WMO	
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

ССМО

ID NL13850.091.06