High risk human papillomavirus detection in semen

Published: 13-12-2010
Last updated: 30-04-2024

Evaluate the prevalence, consistency, and genotype distribution of human papillomavirus (HPV) in semen and to examine the exact localization of HPV (i.e., in the seminal fluid and/or on the membrane or cytoplasm of the sperm cell).Evaluate the...

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

Summary

ID

NL-OMON34492

Source
ToetsingOnline

Brief title
Semen study

Condition

- Viral infectious disorders
- Penile and scrotal disorders (excl infections and inflammations)

Synonym
HPV, Human papillomavirus

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Stichting Research Pathologie

Intervention

Keyword: Genotype distribution, High risk HPV, Semen, Virus transmission

Outcome measures

Primary outcome

Endpoint is the HPV PCR outcome; i.e., presence or absence of hrHPV DNA in

semen.

Secondary outcome

Evaluate the presence of flat penile lesions and the association with the

prevalence of infection with human papillomavirus (HPV) in semen.

Study description

Background summary

Human papillomaviruses (HPVs) are members of the Papillomaviridae family of DNA viruses. More than 100 types have been identified, of which, about 60 types infect the anogenital region. Anogenital HPV types have been further classified into low-risk types (e.g., 6 and 11), which are associated with anogenital warts and mild dysplasia, and high-risk types (e.g., 16, 18, 33 and 45), which are associated with high-grade dysplasia and anogenital cancers, such as cervical and anal carcinoma. Anogenital HPV infections are the most common sexually transmitted infections (STI) with a lifetime risk of 80% in women and most infections are asymptomatic or subclinical. The risk factors that aid the establishment of this infection are multiple sexual partners, prolonged use of oral contraceptives, high degree of parity, lack of circumcision, lack of condom use, smoking, immunosuppresion, co infection with HIV and other sexually transmitted agents. (Foresta et al., 2008c)
Most research has focused on HPV infection in women because of the correlation between HPV infection and cervical cancer. High-risk types of HPV have been detected in 99,7% of cervical carcinomas.(Walboomers et al., 1999) However, as with any other STI, men are implicated in the epidemiological chain of the infection. This suggests that there is a potential large number of men who serve both as a carrier and vector of HPVs of which the oncogenic types have been clearly established as the central cause of cervical cancer. Though, the exact mechanism by which sexual contact promotes virus infection remains unclear.

Besides its central role in cervical carcinogenesis, HPV has been recognized as an important risk factor for several cancers in men, such as anal cancer and penile carcinoma and its precursor lesions; flat penile lesions and penile intraepithelial neoplasia (PIN). Several studies have provided estimates of HPV prevalence among men; however these estimates widely range from 1.3%-72.9%.(Dunne et al., 2006) The prevalence of HPV varies on the basis of sampling, processing and the anatomic site(s) or specimen(s) sampled. The sites most likely to be HPV positive are the glans penis/coronal sulcus and the penile shaft followed by the scrotum and the urethra.(Giuliano et al., 2007;Smith et al., 2007;Nielson et al., 2007) In addition, HPV DNA and RNA have also been found in the ductus deferens, epididymis and testis.(Svec et al., 2003;Martorell et al., 2005)
Interestingly, a few studies have shown that HPV DNA is found in semen.(Chan et al., 1994;Aynaud et al., 2002;Didelot-Rousseau et al., 2007) Green et al.(Green et al., 1991) reported that semen HPV DNA are quite prevalent in males with and without genital warts, although half as prevalent in males without genital warts.. Lai et al.(Lai et al., 1996) confirmed the high rate of presence of HPV DNA in sperm cells. However, it remains to be seen whether the HPV found in semen is merely caused by shedding of infected cells from the urethra, or represents an additional mode of HPV transmission, or both.
Possibly, human papillomaviruses bind to the sperm cell, and exploit the sperm cell as vehicles for dispersal and mucus penetration within the female genital tract. The exact localization of HPV in the different component of semen, i.e. seminal plasma and sperm cells, has received little attention in literature. A recent study using FISH has reported the finding of HPV DNA in the head of the spermatozoa, but it was unclear whether it was integrated into the nucleus.(Foresta et al., 2008a)
The rationale of this pilot study, is that when HPV or HPV genotypes, specifically binds to sperm cells, this would have significant consequences for the understanding of the mode of HPV transmission. Furthermore, this knowledge could influence the results of IVF or ICSI procedures. Therefore, in this study, we set out to investigate the prevalence and genotype distribution of HPV DNA in semen, and its exact localization within the seminal fluid or on the sperm cell. Furthermore, we aim to investigate the consistency of a diagnosed HPV infection in semen, and a possible association with the presence of flat penile lesions.
In case the results of this study show that HPV specifically binds to sperm cells, subsequently, we will perform a larger study on the effects of HPV infections in semen, on the results of IVF- and ICSI procedures.

Study objective

Evaluate the prevalence, consistency, and genotype distribution of human papillomavirus (HPV) in semen and to examine the exact localization of HPV (i.e., in the seminal fluid and/or on the membrane or cytoplasm of the sperm cell).

Evaluate the presence of flat penile lesions and the association with the prevalence of infection with human papillomavirus (HPV) in semen.

Study design

Observational pilot study

Study burden and risks

Risks and burden are linked to the protocol procedures, such as a penile swab and penoscopy. Although these procedures are carried out by medically qualified personnel, they may cause some discomfort to the subjects. However, it is expected that these procedures will generally be well-tolerated. Furthermore, the subjects are asked to turn in 3 semen samples with time intervals of 1 week for detection of hrHPV. The burden is that this will require 3 visits to the outpatient clinic to hand in the samples. Finally, a questionnaire on sexual behaviour is given to the subjects.
Participants will receive a financial compensation of 60 euro for taking part in the study.

Contacts

Public
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
1007 MB Amsterdam
NL
Scientific
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
1007 MB Amsterdam
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Male
18 years of age or older
Sufficient knowledge of the Dutch or English language
Signed informed consent

Exclusion criteria

withdrawal of the informed consent

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):	01-10-2011
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO Date:	13-12-2010
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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	NL32488.000.10