Human papillomavirus (HPV) prevalence among men aged 19-27 years in the Netherlands.

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Ancillary infectious topics
Study type	Observational non invasive

Summary

ID

NL-OMON53219

Source
ToetsingOnline

Brief title
HPV prevalence among young men.

Condition

- Ancillary infectious topics

Synonym
HPV, human papillomavirus

Research involving
Human

Sponsors and support

Primary sponsor: RIVM
Source(s) of monetary or material Support: Ministerie van Volksgezondheid;Welzijn en Sport.

Intervention

Keyword: genital prevalence, HPV, Human papillomavirus, young men

Outcome measures

Primary outcome

The primary study outcomes are the prevalence of genital hrHPV *overall* and types 16 and 18 and the HPV vaccination status after completion of the catch-up campaign.

Secondary outcome

Secondary outcomes include the genital prevalences of HPV types other than types 16 and 18 as well as the prevalence of hrHPV in urine to compare the accuracy of hrHPV detection of self-collected first-void urine with self-collected penile swabs.

Study description

Background summary

A persistent infection with a high-risk human papillomavirus (hrHPV) can cause HPV-related cancer such as cervical, penile or anal cancer. In the Netherlands, a girls-only vaccination (GOV) policy to prevent HPV-related cancer was introduced in 2009. Since 2022, a gender-neutral vaccination (GNV) policy is implemented in which boys and girls are invited for HPV vaccination in the year they turn 10. Additionally, a catch-up campaign for persons aged 19-27 years started in 2023. Such changes in HPV vaccination policy specifically require monitoring and evaluation. While for women the effectiveness of the catch-up campaign can be studied using information from the national population-based cervical cancer screening, for men no such screening for HPV-related cancer and (pre-)cancerous lesions exists yet. At this moment, only projections resulting from e.g. modelling studies can provide insight into the future impact of the catch-up campaign for men. Information on the prevalence of HPV in the general population, especially for men, is limited but relevant for such modelling studies. Also currently, studies evaluating the effectiveness of the GOV programme focus mainly on vaccine effectiveness (VE), and HPV incidence,

prevalence and persistence among women and visitors of sexual health centres. In these studies, the HPV occurrence is measured through genital self-swabs. Considering the young age at which GNV is offered, using genital self-swabs may be less suitable to evaluate the GNV programme. Therefore, alternatives are explored and (first-void) urine is under consideration as a potential easily accessible tool to measure HPV.

Study objective

In this study, we aim to estimate genital HPV prevalences in men aged 19-27 year in the general Dutch population. Also, we aim to link the hrHPV prevalences to the HPV vaccination status after completion of the catch-up campaign to compare the prevalences between men who received the HPV vaccination during the catch-up campaign versus men who did not receive the vaccination. Additionally, we aim to explore if HPV measured in urine can be used as detection method to measure genital hrHPV prevalence in men and whether it might be an applicable indicator of the impact of HPV vaccination in boys to be used in future monitoring studies.

Study design

The study has a cross-sectional design in which participating men will be asked to complete a baseline questionnaire containing questions about demographics and about sexual preferences/behavior. Additionally, men will be asked to take a penile swab and to collect urine (the latter one is optional). After completion of the catch-up campaign, men receive a second short questionnaire to retrieve information about whether they accepted the HPV vaccination during the campaign.

Study burden and risks

Participation in the study is not associated with health risks and only requires some time investment (approximately 35 minutes) from the participants to complete the questionnaire and collect the self-sample(s).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Male
- Born from 1996 up to and including 2003
- Provided informed consent

Exclusion criteria

not applicable

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	26-09-2023
Enrollment:	1495
Type:	Actual

Ethics review

Approved WMO

Date:	21-06-2023
Application type:	First submission
Review commission:	METC NedMec

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	NL84202.041.23