Willingness to receive Human Papilloma Virus (HPV) vaccination in patients after surgical treatment for Cervical Intraepithelial Neoplasia

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24973

Source
Nationaal Trial Register

Health condition

Cervical Intraepithelial Neoplasia

Sponsors and support

Primary sponsor: None
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

Willingness to vaccinate, with or without financial contribution

Secondary outcome

Participants’ common knowledge about HPV infection

Study description

Background summary

Rationale: The Human Papilloma Virus (HPV) is essential in the carcinogenesis of cervical cancer. Among other countries, the Netherlands have implemented a nationwide vaccination programme to reduce HPV infection in girls. However, multiple parents and eligible participants refused the HPV vaccination due to possible safety concerns. Recent studies have examined the tertiary prevention properties of the HPV vaccination. Women who underwent cervical surgery due to HPV-induced precancerous lesions (Cervical Intraepithelial Neoplasia), were vaccinated. They concluded that HPV vaccination reduces subsequent HPV-related diseases. To implement tertiary prevention of cervical cancer, the willingness to vaccinate in the target group should be examined to prevent possible rejection of the HPV vaccination implementation.
Objective: To explore the willingness to receive HPV vaccination in women who were treated with cervical surgery for CIN. In addition, the level of knowledge of HPV in patients with CIN will be examined
Study design: Prospective questionnaire study
Study population: Women who underwent cervical surgery in the Catharina Hospital due to CIN II-III or High-Grade Squamous Intraepithelial Lesions (HSIL) will be included.
Intervention: A 13-item questionnaire will be used.
Main study parameters: Willingness to vaccinate, with or without financial contribution.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The questionnaire will only take approximately 5 minutes of the participants time. Therefore, there is no significant burden or risk for the participants, neither is there a possible benefit.

Study objective

Women will be willing to receive HPV vaccination to reduce the risk of recurrent HPV-related disease

Study design

After surgical treatment for Cervical Intraepithelial Neoplasia

Intervention

13-item questionnaire

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- Cervical intraepithelial neoplasia II or III
- Cervical surgery: Large Loop Excision of the Transformation Zone (LLETZ) and conisation

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- Age < 18 years
- Previous HPV vaccination
- Cervical carcinoma
- Allergy for vaccination
- Poor understanding of the Dutch language

Study design

Design

Study type:	Observational non invasive

Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2020
Enrollment:	126
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL8481
Other	MEC-U : W20.062

Study results