# VACCIN study

Gepubliceerd: 05-08-2019 Laatst bijgewerkt: 19-03-2025

HPV vaccination after LEEP for CIN reduces recurrence.

| | |
|---|---|
| **Ethische beoordeling** | Positief advies |
| **Status** | Werving gestart |
| **Type aandoening** | - |
| **Onderzoekstype** | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON22561

**Bron**
Nationaal Trial Register

**Verkorte titel**
VACCIN

**Aandoening**

Cervical intraepithelial neoplasia (CIN), Human Papilloma Virus (HPV)

### Ondersteuning

**Primaire sponsor:** Erasmus MC
**Overige ondersteuning:** ZonMw
Merck Sharp & Dohme

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

**Primaire uitkomstmaten**

CIN II-III at 24 months

# Toelichting onderzoek

### Achtergrond van het onderzoek

Cervical cancer is preceded by precursor stages: Cervical Intraepithelial Neoplasia, (CIN). These CIN abnormalities are caused by the Human Papilloma virus (HPV) and are mostly found in women in their reproductive age. There is an effective prophylactic vaccine against HPV, given since 2009 in the Netherlands to girls of 12 and 13 years old. This vaccine is very effective against the occurrence of CIN abnormalities in this group. Also, in older women who already had an HPV infection, without CIN abnormalities, the vaccine has shown to be effectively for preventing to develop CIN. The current treatment of CIN II-III (moderate to severe precursor stages) is surgical removal of a part of the cervix, called a Loop Electrosurgical Excision Procedure (LEEP). The recurrence rate or residual rate of a LEEP is up to 17%. A secondary surgical treatment is necessary in these women. Surgical treatments are associated with bleeding, narrowing of the cervix and infection. The biggest problem, with sometimes lifelong consequences, are the obstetric complications, especially premature birth. This becomes more frequent and more serious after repeated surgical intervention. The (repeated) treatment is also a burden of the women and her relatives. There is limited data that shows that prophylactic HPV vaccination after LEEP reduces the chance of recurrence, therefore leading to a reduction in repeated surgical interventions. There are no randomised controlled studies supporting this data.

Objectives:
Evaluate the efficacy of nonavalent HPV vaccination in women with a CIN lesion who will undergo or have undergone a LEEP in preventing recurrent CIN II-III after 24 months.

Study design:
Randomised, double blinded, placebo controlled trial in female patients with CIN II-III and treated with LEEP.

Study population:
The study population exists of adult female patients, diagnosed with (histologically proven) CIN II-III and treated with LEEP and no prior vaccination for HPV.

Intervention:
Three times a 0.5 ml nonavalent HPV vaccination. Comparator: placebo vaccination.

Main study parameters:
Primary outcome: CIN II-III at 24 months
Secondary: high risk HPV presence, cytology, number of re-interventions, cost-effectivity, adverse events, and quality of life.

### Doel van het onderzoek

HPV vaccination after LEEP for CIN reduces recurrence.

### Onderzoeksopzet

September 2019 start inclusion
All inclusions within 24 months.
Follow-up 24 months.

### Onderzoeksproduct en/of interventie

Intervention: Three times a 0.5 ml nonavalent HPV vaccination after LEEP
Comparator: placebo vaccination after LEEP
(Time of intervention: at time of LEEP, at 2 months and 6 months)

## Contactpersonen

### Publiek

Erasmus MC
Ralf van de Laar

+3150032145

### Wetenschappelijk

Erasmus MC
Ralf van de Laar

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## Deelname eisen

### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Women 18 years or older
- Histologically proven CIN II or III
- Patients treated with LEEP (inclusion within 4 weeks after LEEP)

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Prior HPV vaccination
- (Micro-) invasive carcinoma
- Immune-compromised patients
- Pregnancy
- Prior treatment for CIN-lesions
- Insufficient understanding of the Dutch language
- Women allergic to vaccine components

## Onderzoeksopzet

### Opzet

| | |
|---|---|
| Type: | Interventie onderzoek |
| Onderzoeksmodel: | Parallel |
| Toewijzing: | Gerandomiseerd |
| Blindering: | Dubbelblind |
| Controle: | Placebo |

### Deelname

Nederland

| | |
|---|---|
| Status: | Werving gestart |
| (Verwachte) startdatum: | 19-08-2019 |
| Aantal proefpersonen: | 750 |
| Type: | Verwachte startdatum |

### Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

**Wordt de data na het onderzoek gedeeld:** Nog niet bepaald

## Ethische beoordeling

Positief advies

| | |
|---|---|
| Datum: | 05-08-2019 |
| Soort: | Eerste indiening |

# Registraties

## Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 54737
Bron: ToetsingOnline
Titel:

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

| Register | ID |
|---|---|
| NTR-new | NL7938 |
| CCMO | NL66775.078.18 |
| OMON | NL-OMON54737 |

# Resultaten