

# Rijksvaccinatieprogramma LIM cohortstudie 2: HPV monitor

**First published:** 07/03/2022

**Last updated:** 14/03/2024

Study

Planned

## Administrative details

### EU PAS number

EUPAS46107

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### Study ID

46108

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### DARWIN EU® study

No

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### Study countries

 Netherlands

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### Study status

Planned

## Research institutions and networks

## Institutions

### Netherlands Pharmacovigilance Centre Lareb

 Netherlands

**First published:** 05/02/2010

**Last updated:** 19/07/2016

Institution

Outdated

Not-for-profit

ENCePP partner

## Contact details

### Study institution contact

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Study contact

[j.schmitz@lareb.nl](mailto:j.schmitz@lareb.nl)

### Primary lead investigator

Agnes Kant

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 01/02/2022

Actual: 01/02/2022

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**Study start date**

Planned: 01/04/2022

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**Date of final study report**

Planned: 31/03/2025

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Dutch Ministry of Health, Welfare and Sports

## Regulatory

**Was the study required by a regulatory body?**

No

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**Is the study required by a Risk Management Plan (RMP)?**

Not applicable

## Other study registration identification numbers and links

[www.hpvmmonitor.nl](http://www.hpvmmonitor.nl)

## Methodological aspects

### Study type

### Study type list

**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

**Main study objective:**

To investigate the presence of adverse events following immunization (AEFI) for every vaccin, within the Dutch National Immunization Programme, in children between 9 and 10 years of age. In addition, we investigate the impact and course of the AEFIs as well as the risk of recurrence of AEFIs for multidose vaccines.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Anatomical Therapeutic Chemical (ATC) code**

(J07BM02) papillomavirus (human types 16, 18)

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(J07BD52) measles, combinations with mumps and rubella, live attenuated

measles, combinations with mumps and rubella, live attenuated

(J07AM51) tetanus toxoid, combinations with diphtheria toxoid

tetanus toxoid, combinations with diphtheria toxoid

## Population studied

## Age groups

- Children (2 to < 12 years)
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## Estimated number of subjects

5000

## Study design details

### Outcomes

- Which AEFI's occur after each vaccination, - What is the course and impact of these AEFIs - Do AEFI's reccur after multidose vaccinations and if so, which AEFIs? - Are there any riskfactors to experience (recurring) AEFIs?

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### Data analysis plan

- Cross-sectional analysis on the number of experienced AEFI's per vaccin (frequencies) - Longitudinal analyses on the recurrence of AEFI's (compare frequencies for multidose vaccinations) - Regression analysis to investigate risk factors

## Data management

### ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

## Data sources

## **Data sources (types)**

Other

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### **Data sources (types), other**

Prospective patient-based data collection

## **Use of a Common Data Model (CDM)**

### **CDM mapping**

No

## **Data quality specifications**

### **Check conformance**

Unknown

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### **Check completeness**

Unknown

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### **Check stability**

Unknown

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### **Check logical consistency**

Unknown

## **Data characterisation**

### **Data characterisation conducted**

No