Rijksvaccinatieprogramma LIM cohortstudie 2: HPV monitor

First published: 07/03/2022

Last updated: 14/03/2024

Study Planned

Administrative details

EU PAS number

EUPAS46107

Study ID

46108

DARWIN EU® study

No

Study countries

☐ Netherlands

Study status

Planned

Research institutions and networks

Institutions

Netherlands Pharmacovigilance Centre Lareb

Netherlands

First published: 05/02/2010

Last updated: 19/07/2016

Institution | Not-for-profit | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Agnes Kant

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/02/2022

Actual: 01/02/2022

Study start date
Planned: 01/04/2022

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

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

Not applicable

Other study registration identification numbers and links

www.hpvmonitor.nl

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

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

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(J07AM51) tetanus toxoid, combinations with diphtheria toxoid

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Population studied

Age groups

Children (2 to < 12 years)

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?

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

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

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No