HPV vaccines effectiveness to prevent genital warts in Valencia Region, Spain

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Study Ongoing

Administrative details

EU PAS number

EUPAS30769

Study ID

30770

DARWIN EU® study

No

Study countries

☐ Spain

Study description

Genital warts are a frequent sexually-transmitted disease. It has been estimated that about 5–10% of the population will have at least one episode of genital warts during their lifetime1. It has been recently described an overall

annual incidence of genital warts from 160 to 289/100,000 person-years. Over 90% of genital warts are related to HPV6/11. In Europe there are three licensed vaccines containing recombinant HPV L1 capsid proteins. In the Valencian Community in Spain, the quadrivalent HPV vaccine (HPV 6/11/16/18) was used only between 2008 and 2010 and was administered in a three-dose regimen to vaccinate girls when they were 14 years old. Thereafter, the bivalent vaccine AS04-bHPV (HPV 16/18) was used. This change allowed us to perform the first analysis (to our knowledge) of the effectiveness of both HPV vaccines in preventing genital warts in the same population. In the previous population-based study the oldest vaccinated women in our cohort was 19 years old at the end of the follow up period, so we were unable to assess the vaccine impact on cervical cancer as these women did not reach the screening age. Unvaccinated girls and those vaccinated with the bivalent vaccine had the same risk of incidence of genital warts. HPV-related tumors in HIVpositive patients tend to occur at a younger age and at a more advanced stage than in HIV-negative patients. One of our objectives in the present study is to estimate the effectiveness of the HPV vaccines to prevent genital warts in women aged from 14 to 23+ (depending on the date of data extraction) years old. We also propose to assess the incidence and treatment-costs of GW in subjects aged from 14 to 65 years old. Another secondary objective is to estimate the effectiveness of the HPV vaccines to prevent genital warts in IC women aged from 14 to 23+ years old. Finally, towards future studies we aim to explore the precancerous lesions diagnoses in women aged from 14 to 65 years old.

Study status

Ongoing

Research institutions and networks

Institutions

The Foundation for the Promotion of Health and Biomedical Research of Valencia Region (FISABIO)

Spain

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Cintia Munoz-Quiles

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 05/10/2018

Study start date

Actual: 05/11/2018

Data analysis start date
Actual: 05/06/2019

Date of final study report
Planned: 05/06/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

MSD

Study protocol

AIV - FISABIO_HPV_2018_07_VEGW_CMQ_version1.pdf(822.77 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Main study objective:

To estimate the effectiveness of the HPV vaccines to prevent genital warts in women aged from 14 to 23+ years old (depending on the date of data extraction).

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Population-based study

Study drug and medical condition

Medical condition to be studied

Papilloma viral infection

Population studied

Age groups

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Estimated number of subjects

3300000

Study design details

Outcomes

Incident cases of Genital Warts in primary care and outpatient clinics.

Precancerous lesions

Data analysis plan

Crude and adjusted VE overall and in IC population for bivalent and quadrivalent vaccines and the risk of GW in IC subjects respect to IC-free will be estimated by statistical models considering time-dependent variables. Variables that are relevant to the disease or can impact on the incidence of genital warts will be considered.

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)

Administrative healthcare records (e.g., claims)

Electronic healthcare records (EHR)

Other

Data sources (types), other

Exposure registry

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