

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

**First published:** 02/08/2019

**Last updated:** 02/08/2019

Study

Ongoing

## Administrative details

### PURI

<https://redirect.ema.europa.eu/resource/30770>

### 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 lifetime<sup>1</sup>. 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 institution and networks

### Institutions

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

Spain

**First published:** 01/02/2024

Last updated 01/02/2024

Institution

## Contact details

### Study institution contact

Cintia Munoz-Quiles

Study contact

[cinquiles@gmail.com](mailto:cinquiles@gmail.com)

### 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

### Data sources

#### Data sources (types)

Administrative data (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