AIV - FISABIO Impact and risk of Herpes Zoster in immunosuppressed subjects in Valencia Region, Spain

First published: 02/08/2019
Last updated: 01/04/2024

Study | Finalised

Administrative details

PURI
https://redirect.ema.europa.eu/resource/30801

EU PAS number
EUPAS30792

Study ID
30801

DARWIN EU® study
No

Study countries
Spain

Study description
Herpes Zoster is a disease caused by the reactivation of the varicella-zoster virus in situations of decreased cellular immunity. Among the patients with the highest risk of suffering an HZ are patients with advanced age and immunosuppression of different origin and grade. These subjects would be beyond the scope of the only vaccine that currently exists on the market, as it is a live attenuated virus vaccine. An alternative to this type of vaccine is the inactivated subunit vaccine (glycoprotein E). Primary objective: Estimate the incidence of HZ in immunosuppressed subjects ? 18 years in the Valencian Community, between 2009 and 2014, both globally and stratifying by age groups, sex and type of

immunodeficiency. Secondary: Estimate the risk of HZ in immunocompromised subjects compared to immunocompetent subjects, compare the consumption of health resources, the risk of complications and the risk of recurrent HZ. To study the impact of HZ on the underlying pathology (immunosuppression), comparing the six months prior to the first diagnosis of HZ with the six months after said diagnosis. To study the risk of HZ and the consumption of resources in immunocompromised patients in comorbidity with diabetes and / or chronic obstructive pulmonary disease and / or heart failure and / or chronic kidney disease, compared to immunocompetent subjects. To estimate the prevalence of immunosuppressive conditions in the general population prior to the first diagnosis of HZ with the six months after that diagnosis. To study the risk of HZ and the consumption of resources in immunocompromised patients in comorbidity with diabetes and / or chronic obstructive pulmonary disease and / or heart failure and / or chronic kidney disease, compared to immunocompetent subjects. Estimate the risk of suffering a recurrent HZ in immunocompromised and immunocompetent subjects. Estimate the prevalence of immunosuppressive conditions in the general population.

Study status
Finalised

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
Javier Diez-Domingo
Study contact

diez_jav@gva.es
Primary lead investigator
Javier Diez-Domingo
Primary lead investigator

Study timelines

Date when funding contract was signed
Actual:
27/01/2017

Study start date
Actual:
27/02/2017

Date of final study report
Actual:
27/09/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GSK

Study protocol

AIV - FISABIO_HZ_2017_04_IHZIS_JDD.pdf(218.32 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 topic:
Disease /health condition

Study type:
Non-interventional study

Scope of the study:
Disease epidemiology
Other

If ‘other’, further details on the scope of the study
Impact and risk

Data collection methods:
Secondary data collection

Main study objective:
To estimate the incidence of HZ in IS subjects 18 years and older in Valencia Region, from 2009 to 2014, both globally and stratified by age groups, sex and immunodeficiency type (HIV, malignancies, organ transplantation, immunodeficiency disorders and autoimmune diseases)

Study Design

Non-interventional study design
Cohort
Other

Non-interventional study design, other
Population based, retrospective cohort study

Study drug and medical condition

Medical condition to be studied
Immunodeficiency common variable

Population studied

Short description of the study population
Immunosuppressed subjects ? 18 years in the Valencian Community, between 2009 and 2014.

Age groups
Adults (18 to < 46 years)
Adults (46 to < 65 years)
Adults (65 to < 75 years)
Adults (75 to < 85 years)
Adults (85 years and over)

Special population of interest
Immunocompromised

Estimated number of subjects
4382590

Study design details

Outcomes
An incident case of HZ will be considered the first appearance of a HZ-related ICD-9-CM code (053.xx), in either SIA or CMBD (in any position). Any outpatient medical contact or visit, or hospital admission related to HZ will be considered as a medical encounter. Recurrence of HZ will be examined in all HZ incident cases. - Health care resources consumption due to HZ:Outpatient visit.Hospitalizations.Length of hospitalization.Medication.Periods off work.- Health care resources consumption due to IS:Outpatient visits.Hospitalizations.Length of hospitalization.- HZ complications - Post-herpetic Neuralgia- Comorbidities

Data analysis plan
We might expect approx. 4 million subjects to fulfil the inclusion criteria. Internal data from a previous study from our team, using the same health databases from Valencia Region and the same ICD-9 codes showed a prevalence of IS of 11.8% in subjects ? 50 years old. These data correlate with a published work with a large study population of 51 million subjects and a prevalence of IS of 11.9% for subjects ? 50 years old 9. According to this and the published data, the observed prevalence of IS for subjects aged 18 years and older was approx. 7% so, we will expect around 280.000 IS subjects in the present study.

Data management

Data sources

Data sources (types)
Administrative data (e.g. claims)
Drug registry

Electronic healthcare records (EHR)

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
Unknown