Risk of Herpes Zoster in individuals diagnosed with COVID19 infection in the Valencia region of Spain: a retrospective cohort population-based study (AIV_HZ_2021_05_COVIDHZ_AOS)

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Study Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/43811

EU PAS number

EUPAS43810

Study ID

43811

DARWIN EU® study

No

Study countries

Spain

Study description

Based on the potential association between SARS-CoV-2 and HZ, we propose here a study to estimate the risk of HZ in subjects with SARS-CoV-2 infection using Real World Data (RWD). This population-based retrospective dynamic cohort study (meaning that members can leave or be added over time) will be based on eHR databases/registries from the Valencia Region (Valencia 7 Health System Integrated Database (VID) (27). VID allows linking socio-demographic, inpatients, outpatients, specialists, medication, and microbiology databases (among others) at individual level. The study population will consist of all population covered by the Public Health System (over 98%), representing about 5 million persons. As of March 8th, 2021, more than 381,919 confirmed cases of SARS-CoV-2 have been registered in the Valencian Community (4). Together with the VID makes the region of Valencia the ideal candidate to test the proposed hypothesis.

Study status

Planned

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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Primary lead investigator

Alejandro Orrico-Sánchez

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 24/09/2021

Actual: 24/09/2021

Study start date

Planned: 31/03/2022

Date of final study report

Planned: 01/10/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GSK

Study protocol

PROTOCOL_AIV_V5.0.pdf(1.06 MB)

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:

Assessment of risk minimisation measure implementation or effectiveness
Disease epidemiology

Main study objective:
Compare the risk of HZ among individuals 50 years and older with and without laboratory confirmed SARS-CoV2 infection. Compare the risk of HZ among individuals 18 years and older with and without laboratory confirmed SARS-CoV2 infection. Compare the risk of HZ in overall population older than 18 years old in the pandemic period against pre-pandemic period.

Study Design

Non-interventional study design
Cohort

Study drug and medical condition

Medical condition to be studied
Herpes zoster
SARS-CoV-2 test positive

Population studied

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

Renal impaired

Hepatic impaired

Immunocompromised

Estimated number of subjects

4000000

Study design details

Outcomes

Compare the risk of HZ among individuals 50 years and older with and without laboratory confirmed SARS-CoV2 infection. Compare the risk of HZ among individuals 18 years and older with and without laboratory confirmed SARS-CoV2 infection. Compare the risk of HZ in overall population older than 18 years old in the pandemic period against pre-pandemic period. Describe the likelihood of developing HZ after laboratory-confirmation of SARS-CoV2 according to severity of disease.

Data analysis plan

To develop the primary objective, we will compare the incidence of HZ among SARS-Cov-2 free and Sars-Cov-2 laboratory-confirmed subjects 50 years and older during the pandemic period. For this purpose, models using individual patient data or grouped will be implemented.The risk of HZ in subjects with Sars-cov-2 respect to subjects without Sars-Cov-2 will be estimated by a multivariate Poisson or negative binomial model according to applicability assumptions. Individual data will be grouped by SARS-Cov-2 free and Sars-Cov-2 laboratory-confirmed exposure, age, sex and comorbidities. Individual and

grouped data can both be analyzed with the Poisson (or Negative binomial) distribution. Given the usual large size of the cohort, estimation when using grouped data is considerably quicker than when using individual level data and the results for both approaches are remarkably similar. The number of HZ cases by aggregation unit will be compared among SARS-Cov-2 free and lab-confirmed subjects.

Data management

Data sources

Data sources (types)

Administrative healthcare records (e.g., claims)

Disease registry

Drug dispensing/prescription data

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

No