Case-control study based on hospitals about seasonal influenza vaccine effectiveness to avoid income associated with laboratory-confirmed influenza virus infection in subjects aged 18 or more during 2011-2020 seasons and the disease burden due to respiratory viruses in patients of any age admitted into the hospitals included in the study (AIV - Fisabio) (HBTNCC)

First published: 11/10/2018

Last updated: 29/07/2019

Study Ongoing

Administrative details

EU PAS number

EUPAS25599

Study ID

30695

DARWIN EU® study

No

Study countries

Spain

Study description

Influenza and vaccination against influenza have a profound impact on society. Thus, knowing the illness burden due to influenza and the impact of current vaccination programs is necessary to take present and future decisions. On the other hand, given the characteristics of the virus and the vaccine, this information must be generated in a timely and continuous manner, so it is convenient to study several flu seasons in large samples of the population.For this purpose, estimates of the influenza vaccine effectiveness based on information from sentinel medical networks using case-control studies or screening methods are useful.These estimates must be timely, robust and reliable, so that the parts involved can take decisions and assessing the impact of the measures adopted have useful information and quality. This need justifies the performance of phase IV post-authorization effectiveness studies based on the impact of the infection and preventive measures on hospital admissions due to influenza.In our case, it is a case-control study based on a hospital-based system of active surveillance of incident income where the presence of influenza infection is verified with the study's own resources. The methodology of detection of virus infection also allows carrying out a study of the burden of the disease by detecting the incidental income associated with respiratory viruses.

Study status

Ongoing

Research institutions 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: 05/11/2024

Institution

Hospital General Universitario de Alicante (ISABIAL)

First published: 01/02/2024

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Institution

Hospital General Alicante, Hospital General Castellón, Hospital La Fe Valencia, Hospital Doctor Peset Valencia

Contact details

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Primary lead investigator

Javier Díez-Domingo

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 03/09/2018

Actual: 03/09/2018

Study start date

Planned: 10/09/2018

Actual: 10/09/2018

Date of final study report

Planned: 31/10/2019

Sources of funding

- Pharmaceutical company and other private sector
- Other

More details on funding

Sanofi Pasteur S.A., FISABIO

Study protocol

HBTNCC_2018_MP_v 1.3_30082018.pdf(3.03 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:

Disease epidemiology

Effectiveness study (incl. comparative)

Main study objective:

To measure seasonal influenza vaccine efectiveness to avoid laboratory-confirmed entries in adults 18 years of age or older.To measure disease burden due to respirartory viruses in patients of all ages.

Study Design

Non-interventional study design

Case-control

Study drug and medical condition

Medical condition to be studied

Influenza

Influenza like illness

Population studied

Age groups

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

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

Pregnant women

Estimated number of subjects

12000

Study design details

Data analysis plan

Study of hospital-based cases and controls and active epidemiological surveillance of income related to respiratory viruses.

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.

Composition of steering group and observers

Organización y responsabilidades HBTNCC 2018.pdf(202.27 KB)

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