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





## Administrative details

#### **EU PAS number**

**EUPAS25599** 

### **Study ID**

30695

#### **DARWIN EU® study**

No

### **Study countries**

Spair
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#### 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:** 31/10/2025

Institution

Hospital General Universitario de Alicante (ISABIAL)

First published: 01/02/2024

**Last updated:** 01/02/2024

Institution

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

## Contact details

**Study institution contact** 

# Ainara Mira-Iglesias mira\_ain@gva.es

Study contact

mira ain@gva.es

### **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 laboratoryconfirmed 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 stability**

**Check conformance** 

Unknown

## **Check logical consistency**

Unknown

# Data characterisation

#### **Data characterisation conducted**

No