

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

### PURI

<https://redirect.ema.europa.eu/resource/30695>

### EU PAS number

EUPAS25599

**Study ID**30695

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**DARWIN EU® study**No

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**Study countries**☐ Spain

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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.

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## 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

### Study institution contact

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Study contact

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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

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### Study start date

Planned: 10/09/2018

Actual: 10/09/2018

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### 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

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**Is the study required by a Risk Management Plan (RMP)?**

Not applicable

## Methodological aspects

### Study type

### Study type list

**Study type:**

Non-interventional study

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**Scope of the study:**

Disease epidemiology

Effectiveness study (incl. comparative)

**Main study objective:**

To measure seasonal influenza vaccine effectiveness to avoid laboratory-confirmed entries in adults 18 years of age or older. To measure disease burden due to respiratory 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)

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### **Special population of interest**

Renal impaired  
Hepatic impaired  
Immunocompromised  
Pregnant women

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### **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

### **Composition of steering group and observers**

[Organización y responsabilidades HBTNCC 2018.pdf](#)(202.27 KB)

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## Use of a Common Data Model (CDM)

**CDM mapping**

No

Data quality specifications

**Check conformance**

Unknown

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**Check completeness**

Unknown

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**Check stability**

Unknown

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**Check logical consistency**

Unknown

Data characterisation

**Data characterisation conducted**

No