

# Spatio-temporal impact of Rotavirus vaccine coverage on Rotavirus Hospitalizations in the Valencia Region, Spain

**First published:** 29/07/2019

**Last updated:** 02/07/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS30702

---

### Study ID

30703

---

### DARWIN EU® study

No

---

### Study countries

 United Kingdom

---

### Study status

Finalised

## 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

## Contact details

### Study institution contact

Mónica López-Lacort [mlopezlacort@gmail.com](mailto:mlopezlacort@gmail.com)

Study contact

[mlopezlacort@gmail.com](mailto:mlopezlacort@gmail.com)

### Primary lead investigator

Javier Díez-Domingo

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 25/10/2017

Actual: 25/10/2017

---

**Study start date**

Planned: 13/12/2017

Actual: 13/12/2017

---

**Data analysis start date**

Planned: 02/01/2018

Actual: 02/01/2018

---

**Date of interim report, if expected**

Planned: 30/08/2018

Actual: 30/08/2018

---

**Date of final study report**

Planned: 30/09/2018

Actual: 30/09/2018

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

MSD

## Study protocol

[Protocolo\\_JDD-ROT-2017-01.pdf](#) (495.52 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

Human medicinal product

---

**Study type:**

Non-interventional study

---

**Scope of the study:**

Effectiveness study (incl. comparative)

Other

**If 'other', further details on the scope of the study**

Post-licensure vaccine impact study

**Data collection methods:**

Secondary use of data

---

**Main study objective:**

- To estimate spatio-temporal impact of rotavirus vaccine coverage on rotavirus acute gastroenteritis hospitalizations among Valencia Region's population aged less than 3 years.- To assess space-time variation in hospitalized acute rotavirus gastroenteritis risk.- To assess space-time variation in rotavirus vaccine coverage.

## Study Design

**Non-interventional study design**

Other

---

**Non-interventional study design, other**

Retrospective, population-based study

## Study drug and medical condition

**Medical condition to be studied**

Rotavirus infection

## Population studied

**Short description of the study population**

Valencia Region's children less than 3 years during the study period.

---

**Age groups**

- Preterm newborn infants (0 - 27 days)

- Term newborn infants (0 - 27 days)
  - Infants and toddlers (28 days - 23 months)
- 

### **Estimated number of subjects**

721741

## Study design details

### **Outcomes**

- Rotavirus acute gastroenteritis hospitalization: hospitalization with a discharge diagnosis of enteritis due to rotavirus (ICD-9-CM code 008.61) in any diagnosis position. - Acute gastroenteritis hospitalization: hospitalization with a discharge diagnosis of gastroenteritis-associated episode (ICD-9-CM codes 001-009, 558.9, 787.91) in any diagnosis position.

---

### **Data analysis plan**

We evaluate the spatio-temporal impact of vaccination on rotavirus hospitalization rates (response variable) by a Bayesian spatio-temporal logistic regression contemplating gender, age, health department, bi-annual periods and health care district. To evaluate the space-time behavior of rotavirus/ hospitalization rates and vaccine coverage, we model by the Besag-York-Mollié model the following smoothed risk estimates: the standardized hospitalization ratio and the standardized vaccination rate, considering bi-annual periods and health care districts.

## Documents

### **Study results**

[reportFV.pdf](#) (1.02 MB)

---

## Data management

ENC 000 000 000

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.

## Data sources

### Data sources (types)

[Administrative healthcare records \(e.g., claims\)](#)

[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