

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

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Study

Finalised

## Administrative details

### Contact details

**Study institution contact**

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Study contact

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**Primary lead investigator**

Javier Díez-Domingo

Primary lead investigator

**PURI**

<https://redirect.ema.europa.eu/resource/30703>

**EU PAS number**

EUPAS30702

**Study ID**

30703

**DARWIN EU® study**

No

## Study countries

United Kingdom

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## Study status

Finalised

# Research institution and networks

## Institutions

The Foundation for the Promotion of Health and Biomedical Research of Valencia Region (FISABIO)

Spain

**First published:** 01/02/2024

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Institution

## Study timelines

### Date when funding contract was signed

Planned:

25/10/2017

Actual:

25/10/2017

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### Data collection

Planned:

13/12/2017

Actual:

13/12/2017

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### Start date of data analysis

Planned:

02/01/2018

Actual:

02/01/2018

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### Date of interim report, if expected

Planned:

30/08/2018

Actual:  
30/08/2018

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#### **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

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**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

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**Study type:**

Non-interventional study

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**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 data collection

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**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 r

## Study Design

**Non-interventional study design**

Other

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**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.

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## Age groups

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

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## 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.

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## 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

## Results tables

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

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# Data management

## Data sources

### Data sources (types)

[Administrative data \(e.g. claims\)](#)

[Drug registry](#)

[Electronic healthcare records \(EHR\)](#)

## Use of a Common Data Model (CDM)

**CDM mapping**

No

Data quality specifications

**Check conformance**

Unknown

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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**

Unknown