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

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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

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Institution

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: 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

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.

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