

Impact of Rotavirus Vaccination on Acute Gastroenteritis outpatient and emergency department visits using “Real World Data” from the Valencia Region, Spain

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Study

Ongoing

Administrative details

EU PAS number

EUPAS30772

Study ID

30773

DARWIN EU® study

No

Study countries

☐ Spain

Study description

Acute gastroenteritis is a frequent disease, with rotavirus being the main cause in children under 5 years of age. Every year, RV accounted for 231 deaths, more than 87,000 hospitalisations, and nearly 700,000 outpatient visits in Europe. In addition to the clinical impact, these rotavirus-associated events result in increased medical expenses, lost productivity, and other costs to society and families. In Spain, rotavirus vaccines have been available since 2006 (RV1) and 2007 (RV5). Benefits of rotavirus vaccines have been widely studied. These kind of studies in Spain have separately, and for varied populations and time periods, analysed vaccines impact on RVAGE-hospitalizations (up to 71% reduction in infants), all-cause AGE hospitalizations (up to 39% reduction in infants) (11) and effectiveness (over 85% effective against rotavirus hospitalization among young children). The effects of rotavirus vaccine on ED and outpatients visits are not widely documented. This study aims to provide for the first time a comprehensive evaluation of the impact of rotavirus vaccines on ED and outpatient utilization among children <5 years of age of the Valencia Region, for acute gastroenteritis. This approach will provide estimates of the economic impact of rotavirus vaccines on outpatients and ED visits and the national health system associated costs. The Valencia Region accounts with a network of health care databases linked together, which allow the linkage of ED and outpatients registries with the vaccine status at individual level. Secondary objectives: - To estimate the risk of AGE-O and AGE-ED consultations between vaccinated and nonvaccinated children aged less than 5 years from the Valencia Region.- To estimate the economic impact of rotavirus vaccines on AGE-O and AGE-ED visits and the national health system associated costs among children aged less than 5 years from the Valencia Region.

Study status

Ongoing

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

Alejandro Orrico-Sánchez orrico_ale@gva.es

Study contact

orrico_ale@gva.es

Primary lead investigator

Alejandro Orrico-Sánchez

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 28/11/2018

Study start date

Actual: 28/12/2018

Data analysis start date

Planned: 28/07/2019

Date of final study report

Planned: 28/07/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

MSD

Study protocol

[AIV - FISABIO _Rota_ED&PC_AOS_2018_v2.pdf](#) (950.26 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 type:

Non-interventional study

Scope of the study:

Other

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

Post-licensure vaccination impact study

Main study objective:

To estimate the impact of rotavirus vaccination on all-cause acute gastroenteritis outpatient (AGE-O) and Emergency Department (AGE-ED) consultations among children aged less than 5 years from the Valencia Region.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Observational retrospective study

Study drug and medical condition

Medical condition to be studied

Gastroenteritis rotavirus

Population studied

Age groups

- Children (2 to < 12 years)

Estimated number of subjects

600000

Study design details

Outcomes

1- AGE-O: all-cause acute gastroenteritis outpatients visits. 2- AGE-ED: all-cause acute gastroenteritis emergency department visits. 3- AGE-O or AGE-ED: all-cause acute gastroenteritis outpatient and emergency department visits.

Data analysis plan

A descriptive analysis will be developed, yearly outpatients and ED rates will be calculated as the number of AGE-O or AGE-ED visits divided by the total population by gender, age, health department and in general.

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)

Electronic healthcare records (EHR)

Other

Data sources (types), other

Exposure registry

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

No