QALY loss due to respiratory syncytial virus (RSV) infection in children younger than 2 years and their relatives in the Valencian Community and Catalonia (AIV-Fisabio) (QALYs lost due to RSV)

First published: 21/02/2019

Last updated: 29/07/2019

Study Ongoing

Administrative details

EU PAS number

EUPAS27465

Study ID

30698

DARWIN EU® study

No

Study countries

☐ Spain

Study description

Respiratory syncytial virus (RSV) is the most important cause of respiratory infection in children younger than 2 years and the cause of the highest number of hospitalizations. Different vaccine development programs for infant or pregnant women are in advanced stages (Phase II / III), so it is estimated that this vaccine could be a reality soon. Pharmaeconomic studies allowing the estimation of the potential impact of these vaccines are required in advance. The reference analysis for the economic-sanitary evaluation of a new health intervention is cost-utility. Their results are expressed in quality-adjusted life-year (QALY), where the utility evaluates the condition of the disease to the health-related quality of life (HRQOL). The few existing studies show that child vaccination against RSV could be cost-effective in other countries. However, they obtained useful data using other countries' QALYs literature. So far there are no available studies estimating QALYs or utilities loss due to RSV infection in children less than 2 years of age (the range of age where the incidence is higher), nor CUA of RSV vaccines candidates available in Spain. As a previous step, it is a priority to establish an estimate of the loss of HRQOL due to RSV in children younger than 2 years and their relatives, measured through utility (QALY) at the national level. This project includes a prospective, multicenter and observational study among Spanish children less than 24 months of age, recruited in different primary care centers and hospitals of Valencian Community and Catalonia, where QALYs of RSV-infected children and their parents will be evaluated through novel health utilities questionnaire and method. The study will be contribute to generate valid data for the future pharmacoeconomic analysis of the vaccine, which will be necessary for decision making and the establishment of recommendations on the use of the vaccine against RSV in Spain.

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 Lluís Alcanys Xativa, Centro Atención Primaria de Burriana II Castellón, Centro Atención Primaria de L'Eliana Valencia, Centro Atención Primaria de Just Ramirez Valencia, Centro Atención Primaria de Ausias March Xativa, Centro pediátrico Medinfant Barcelona, Centro Atención Primaria de Drassanes Barcelona, Centro Atención Primaria Valldoreix Barcelona, Centro de Atención Primaria Sant Cugat del Vallés Barcelona, Centro Atención Primaria Terrasa Sud Barcelona

Contact details

Study institution contact

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Primary lead investigator

Alejandro Orrico-Sánchez

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/07/2018

Actual: 01/07/2018

Study start date

Planned: 01/12/2018

Actual: 01/12/2018

Date of final study report

Planned: 30/11/2019

Sources of funding

- Other

More details on funding

Regional Grant

Study protocol

PROTOCOLO DE ESTUDIO_1.4.pdf(347.14 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:

Disease epidemiology

Main study objective:

QALY loss due to respiratory syncytial virus (RSV) infection in children younger than 2 years and their relatives in the Valencian Community and Catalonia

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Prospective, multicenter and observational study

Study drug and medical condition

Medical condition to be studied

Respiratory syncytial virus infection

Population studied

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

100

Study design details

Data analysis plan

Prospective and observational study and active surveillance during the epidemiological season

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.

Composition of steering group and observers

Equipo investigador.pdf(442.99 KB)

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

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