An epidemiological investigation of high-risk children for Respiratory Syncytial Virus infections - RWE palivizumab utilization as a RSV preventive treatment in Lazio (Italy)

First published: 07/12/2022

Last updated: 23/04/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS49568

Study ID

49569

DARWIN EU® study

No

Study countries

Italy

Study description

The overall objective of the study will be to perform a descriptive analysis of a series of aspects related to respiratory syncytial virus infection in high-risk children, such as drug utilization, hospitalizations and related hospital procedures.

Study status

Ongoing

Research institutions and networks

Institutions

Department of Epidemiology of the Regional Health Service - Lazio

Italy

First published: 23/03/2010

Last updated: 22/06/2018

Institution | Outdated | EU Institution/Body/Agency | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Belleudi Valeria

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 23/06/2022

Actual: 23/06/2022

Study start date
Planned: 27/10/2022

Actual: 27/10/2022

Date of final study report
Planned: 31/12/2022

Sources of funding

- Other

More details on funding

IQVIA Solutions SPA

Study protocol

Protocol_RSV_Palivizumab.pdf (505.02 KB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Other study registration identification numbers and links

Prot. N. 1133/CE Lazio 1

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Drug utilisation

Main study objective:

The overall objective of the study will be to perform a descriptive analysis of a series of aspects related to respiratory syncytial virus infection in high-risk children, such as drug utilization, hospitalizations and related hospital

procedures.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Respiratory tract 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

8000

Study design details

Outcomes

1. Palivizumab utilization (presence or absence of palivizumab prophylaxis, number of prescriptions, adherence) 2. In children with Bronchopulmonary Dysplasia, Congetinal Heart Disease and in preterm populations, describe the health-care resource utilization up to 24 months after birth: hospitalizations, related hospital procedures and drug consumption

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Data analysis plan

Descriptive analysis will be performed on three different cohorts of high-risk children for RSV severe infection (children with BPD, children born with CHD and children born preterm (≤29 and 30-35 WGA). All infants will be observed from index date (date of birth will be defined as index date) until the end of follow-up (maximum 24 months after birth day), end of study. Descriptive statistics will be defined by cohort and per year of birth and stratified by palivizumab use and WGA (according to data availability). Categorial variables will be presented as counts and percentages, while continuous variables will be presented as mean and standard deviation or median and interquartile range according to data distribution. Incidence and prevalence of hospitalizations for each RSV season will be calculated.

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 source(s)

Drug claims information system

Hospital Information System

Healthcare Emergency Information System

Data source(s), other

Lazio Administrative Database Italy

Data sources (types)

Administrative healthcare records (e.g., claims)

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