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





### Administrative details

#### **PURI**

https://redirect.ema.europa.eu/resource/49569

#### **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**



## Contact details

**Study institution contact** 

#### Valeria Belleudi

Study contact

v.belleudi@deplazio.it

#### 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

## 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

#### Data analysis plan

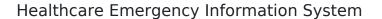
Descriptive analysis will be performed on three different cohorts of high-risk children for RSV severe infection (children with BPD, children born with CHD and children born preterm (≤29 and 30-35 WGA). All infants will be observed from index date (date of birth will be defined as index date) until the 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

#### Data sources

#### Data source(s)

Drug claims information system Hospital 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