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

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 institution and networks

Institutions

Department of Epidemiology of the Regional Health Service - Lazio

Italy
First published: 23/03/2010
Last updated
22/06/2018

Institution

EU Institution/Body/Agency

ENCePP partner

Contact details

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Study contact

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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

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 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 data (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