DARWIN EU® Age specific incidence rates of RSV related disease in Europe

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Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/107880

EU PAS number

EUPAS107708

Study ID

107880

DARWIN EU® study

Yes

Study countries

Estonia

France

Germany

Spain

United Kingdom

Study description

Rationale and Background: Severe acute respiratory infection caused by respiratory syncytial virus (RSV) poses a global health threat, especially impacting children under 5 and older adults, leading to significant morbidity and mortality. The ongoing development of RSV vaccines underscores the critical need for accurate information on RSV burden in high-risk groups, essential for continuous benefit/risk profile assessment. This study aims to provide crucial insights into age-specific incidence rates of RSV-related disease in Europe, contributing to ongoing efforts in comprehending and managing RSV infection burdens.

Research question: What are the age-specific disease frequencies, hospitalisation rates, and mortality rates of RSV infection in European countries over the past decade?

Study objectives: To estimate RSV-related hospitalization rates and duration, proportions of RSV-related ICU admissions and co-infection with other respiratory pathogens, as well as RSV-related mortality rates.

Study status

Finalised

Research institution and networks

Networks

Data Analysis and Real World Interrogation Network (DARWIN EU®)

Belgium

Croatia

Denmark

Estonia

Finland

France

Germany

Hungary

Netherlands

Norway

Portugal

Spain

United Kingdom

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Network

Contact details

Study institution contact

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Study contact

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Primary lead investigator

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Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 15/09/2023

Actual: 15/09/2023

Study start date

Planned: 01/01/2013

Actual: 01/01/2013

Date of final study report

Planned: 31/12/2023

Actual: 27/02/2024

Sources of funding

- EMA

Study protocol

DARWIN_EU_D2.2.3_Protocol_P2_C1-011_RSV_v2.1.pdf(1.02 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Study design:

A cohort study will be conducted using routinely collected health data from 6 databases.

Main study objective:

To estimate the incidence of RSV related hospitalizations and the prevalence of RSV co infections with other respiratory pathogens specifically Influenza Viruses Rhinoviruses SARS CoV 2 Parainfluenza Viruses Adenoviruses Metapneumovirus and Enteroviruses in the general population stratified by year and age groups.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Respiratory syncytial virus infection

Respiratory syncytial virus bronchiolitis

Respiratory syncytial virus bronchitis

Influenza

H1N1 influenza

Pneumonia

Upper respiratory tract infection

Additional medical condition(s)

Acute bronchiolitis due to respiratory syncytial virus, Pneumonia due to respiratory syncytial virus, Acute respiratory syncytial virus bronchitis, Bronchopneumonia due to respiratory syncytial virus, Healthcare associated respiratory syncytial virus disease, Positive sputum culture for hRSV (Human respiratory syncytial virus), Respiratory syncytial virus laryngotracheobronchitis, Respiratory syncytial virus pharyngitis, Bronchiolitis caused by influenza virus

Population studied

Age groups

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

22700000

Study design details

Outcomes

RSV related hospitalization ICU admission mortality rate and co infection with a range of other respiratory pathogens including Influenza Viruses Rhinoviruses SARS CoV 2 Parainfluenza Viruses Adenoviruses Metapneumovirus and Enteroviruses.

Data analysis plan

Analyses will be conducted separately for each database. Before study initiation test runs of the analytics are performed on a subset of the data sources or on a simulated set of patients and quality control checks are performed. Once all the tests are passed the final package is released in the version controlled Study Repository for execution against all the participating data sources. The data partners locally execute the analytics against the OMOP CDM in R Studio and review and approve the by default aggregated results before returning them to the Coordination Centre. Sometimes multiple execution iterations are performed and additional fine tuning of the code base is needed. A service desk will be available during the study execution for support. The study results of all data sources are checked after which they are made available to the team and the Study Dissemination Phase can start. All results are locked and timestamped for reproducibility and transparency.

Documents

Study report

DARWIN_EU_D2.2.4_Report_P2-C1-011_RSV_v2.2_Public.pdf(1.45 MB)

Data management

Data sources

Data source(s)

Institut Municipal d'Assistència Sanitària Information System

Clinical Practice Research Datalink (CPRD) GOLD

IQVIA Disease Analyzer Germany

The Information System for Research in Primary Care (SIDIAP)

Estonian Biobank

Clinical Data Warehouse of the Bordeaux University Hospital

Data sources (types)

Electronic healthcare records (EHR)

Other

Use of a Common Data Model (CDM)

CDM mapping

Yes

CDM Mappings

CDM name

OMOP

CDM website

https://www.ohdsi.org/Data-standardization/

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No