

Epidemiology of Respiratory Syncytial Virus Infections: Retrospective Data to Estimate the Disease Burden in Türkiye

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Study

Finalised

Administrative details

EU PAS number

EUPAS1000000487

Study ID

1000000487

DARWIN EU® study

No

Study countries

☐ Türkiye

Study description

Respiratory syncytial virus (RSV) is a major cause of hospitalisation in newborns, but the risk of infection remains for all children.

In Turkey, where the annual neonatal cohort is approximately 1,079,000, including 149,000 infants with prematurity or comorbid conditions, data on RSV incidence remains scarce.

Even though 98.5% of the population is covered by Social Security Insurance (SSI) and most childhood vaccines are included in the National Immunisation Programme (NIP), public health policy on RSV remains limited due to gaps in real-world data.

Currently, the hospitalisation rate for RSV-positive lower respiratory tract infection (LRTI) is estimated at 7.8 per 1000 infants based on one study. However, the outpatient burden is unknown because RSV testing is not covered in public hospitals, hindering proper diagnosis and surveillance. The lack of data also affects prevention strategies - although palivizumab is available, reimbursement is limited to certain high-risk groups, potentially underestimating the true burden of RSV hospitalisations and associated healthcare costs.

This study aims to fill these data gaps by providing comprehensive epidemiological information on RSV in both inpatient and outpatient settings. A clearer understanding of the morbidity, mortality, and direct costs associated with RSV will facilitate evidence-based policy decisions, helping clinicians and policymakers better evaluate prevention strategies.

With robust real-world data, this study will contribute to the discussion on the expansion of RSV prevention programmes under the NIP in Turkey and serve as a model for other countries in Eurasia to develop national recommendations for RSV prevention.

Study status

Finalised

Research institutions and networks

Institutions

Traverse Health

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Contact details

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Study timelines

Date when funding contract was signed

Planned: 22/10/2024

Actual: 22/10/2024

Study start date

Planned: 22/10/2024

Actual: 22/10/2024

Date of final study report

Planned: 31/12/2024

Actual: 31/12/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

This study was sponsored by Sanofi

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 topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Data collection methods:

Secondary use of data

Study design:

This retrospective, multi-center study will analyze 994 children under 5 admitted to 19 Acibadem hospitals in Türkiye with laboratory-confirmed RSV from June 2022 to June 2024, assessing clinical features, severity, management, and outcomes of RSV cases.

Main study objective:

The main aim of this study is to comprehensively describe the clinical features, disease severity, treatment and outcomes in children under 5 years of age admitted to Acibadem hospitals in Turkey with laboratory-confirmed RSV disease.

This includes analyses of baseline disease characteristics such as ICU admission, use of invasive and non-invasive ventilation and other resuscitation indicators.

Secondary objectives

Quantify RSV diagnostic testing and coding: To assess the frequency of RSV diagnostic testing and coding in hospitalised children focusing on identifying

potential underdiagnosis of RSV, especially as diagnostic tests are not always covered in the outpatient setting, which may lead to missed diagnosis.

The proportion of RSV+ LRTI diagnoses: Determine the proportion of RSV-positive lower respiratory tract infections (LRTIs) among all LRTI diagnoses in outpatient, inpatient, intensive care unit and emergency department (ED) settings. This will provide insight into how often RSV is identified as a cause of LRTI in different healthcare settings.

Comparison of the burden of RSV: Compare the burden of RSV in children with and without major risk factors (e.g., preterm birth, congenital heart disease, chronic lung disease) to assess whether the burden of disease is greater for these children and whether outcomes are more severe.

comorbidities and complications: Assess comorbidities and complication rates in RSV patients, including assessing the need for interventions such as oxygen therapy, mechanical ventilation, or use of antibiotics and steroids.

Comparison with national data: Compare the study results with national-level data (e.g. from published studies or open-access databases) to get a broader picture of the burden of RSV in Turkey. This will include an assessment of RSV-related outpatient data, which are often under-represented in studies due to a lack of out-of-hospital testing coverage.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Retrospective analysis of pre-existing data

Study drug and medical condition

Medical condition to be studied

Respiratory syncytial virus infection

Population studied

Short description of the study population

The study will include 994 children under five years of age admitted to Acibadem hospitals across Turkey between 1 June 2022 and 1 June 2024 with laboratory-confirmed RSV disease.

The study population includes:

- > Children with RSV-associated respiratory infections requiring outpatient, emergency department (ED), inpatient or intensive care unit (ICU) treatment.
- > Infants with and without major risk factors including prematurity, congenital heart disease and congenital lung disease.
- > Patients from 19 Acibadem hospitals, representing a diverse cross-section of paediatric RSV cases in different healthcare settings.

No exclusion criteria were defined for this study, providing a comprehensive assessment of the burden of RSV among hospitalised children in Turkey.

Age groups

Neonate

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

Study design details

Setting

Persons:

Children under 5 years of age who were admitted to Acibadem hospitals across Turkey with a laboratory-confirmed diagnosis of respiratory syncytial virus (RSV) between 1 June 2022 and 1 June 2024 were included in the study. The total number of participants was estimated at 994 children. The cohort included both healthy children and those with underlying risk factors such as premature birth, congenital heart defects, and chronic lung disease.

Location:

The study was conducted across 19 Acibadem hospitals located in various regions of Turkey. These hospitals represented a well-distributed sample, ensuring coverage of multiple geographical areas and a variety of clinical settings, including outpatient, emergency department (EU), inpatient, and intensive care unit (ICU) care.

Time Period:

Data were collected retrospectively from 1 June 2022 to 1 June 2024, covering a two-year period. This time frame ensured that relevant RSV cases were captured, accounting for the seasonal fluctuations in RSV incidence rates.

Selection Criteria:

> Inclusion Criteria: All children under 5 years of age who were admitted to Acibadem hospitals during the study period with a confirmed RSV diagnosis via laboratory tests were included.

> Exclusion Criteria: No exclusion criteria were defined, allowing the study to include the entire population of children hospitalized for RSV.

The study incorporated several clinical variables, including:

- > Severity of illness, such as ICU hospitalization, ventilation type (invasive vs. non-invasive), and the need for additional treatments (e.g., oxygen therapy, antibiotics, steroids).
- > Demographic information, including comorbidities and major risk factors (e.g., preterm birth, congenital heart disease).

RSV testing and coding frequency, which helped to identify underreporting or missed diagnoses in various clinical settings.

Outcomes

Clinical Features

Medical Comorbidities and Birth History

RSV Testing and Coding Frequency

Palivizumab Immunoprophylaxis (if recorded)

Emergency Unit/Outpatient Clinic Administration Ratios

Hospitalization and ICU Ratios

Interventions (including oxygen therapy, antibiotics, steroids, etc.)

Investigations (blood analysis, chest radiograph, CT, lumbar puncture, etc.)

Outcomes (hospitalization, length of stay, death)

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 sources (types)

Electronic healthcare records (EHR)

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Not applicable