DARWIN EU® -Drug utilisation of salbutamol products for inhalation and therapeutic alternative inhalation products

First published: 03/12/2024

Last updated: 11/08/2026

Study Finalised

Administrative details

EU PAS number

EUPAS1000000403

Study ID

1000000403

DARWIN EU® study

Yes

Study countries

- Croatia
- Denmark
- Germany
- Netherlands

Spain

United Kingdom

Study description

Salbutamol is essential for managing asthma and chronic obstructive pulmonary disease (COPD) due to its rapid bronchodilation effects. The rising prevalence of these conditions in Europe, driven by aging populations and worsening air quality, has led to increased demand for salbutamol, especially in urban areas.

A shortage would severely impact patient care, leading to challenges in managing acute symptoms and increased strain on alternative therapies, which are not as effective for immediate relief.

The aim of the study is to understand if salbutamol (inhaled formulation) use has been increasing over the last few years in Europe which will in turn inform a potential risk of shortage. And secondly to understand the impact of the shortage of salbutamol inhaled formulations on therapeutic alternative inhalation products. This exercise falls under preparedness and prevention activities.

Study status

Finalised

Research institutions and networks

Institutions

Department of Medical Informatics - Health Data Science, Erasmus Medical Center (ErasmusMC)

Netherlands

First published: 03/11/2022

Last updated: 02/05/2024

Institution | Educational Institution | ENCePP partner

Networks

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

- Belgium
- Croatia
- Denmark
- Estonia
- Finland
- France
- Germany
- Greece
- Hungary
- Italy
- Lithuania
- Netherlands
- Norway
- Poland
- Portugal
- Spain
- Sweden

United Kingdom

United States

First published: 01/02/2024

Last updated: 05/11/2026

Network

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Marzyeh Amini

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/10/2024

Actual: 01/10/2024

Study start date

Planned: 01/10/2024

Actual: 01/10/2024

Date of final study report
Planned: 31/01/2025

Actual: 30/10/2025

Sources of funding

- EMA

Study protocol

DARWIN EU_Protocol_P3-C1-016_DUS_Salbutamol_V3.pdf (787.64 KB)

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 topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Study design:

A cohort study will be conducted using routinely collected health data from 7 databases. The study will comprise two consecutive parts:

• A population-level cohort study

• Patient-level characterisation study

Main study objective:

1. To describe the overall (i.e. all drug formulations combined) rate of prescribing inhaled salbutamol (irrespective of type of formulation) by calendar time (month, year). Monthly prescribing rates will be provided by database and healthcare setting (inpatient/outpatient).

2. To describe the rate of prescribing inhaled salbutamol by type of formulation and calendar time (year, month). Monthly prescribing rates will be provided by database and healthcare setting.

3. To describe the rate of prescribing other inhaled alternatives and oral salbutamol by calendar time (month, year). Monthly prescribing rates will be provided by database and healthcare setting.

4. To describe characteristics of individuals treated with inhaled salbutamol in

terms of indication of use, sex and age (in age categories) stratified by formulation and provided by database and healthcare setting.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name, other

(1) salbutamol inhalation products (administrated using the following devices: dry powder inhalers (DPIs), metered dose inhalers (MDIs), nebuliser solution), (2) Short-acting Beta-2 agonists (SABA) other than salbutamol (terbutaline, fenoterol), (3) short acting anticholinergic drugs (ipratropium bromide, oxitropium bromide), (4) fixed combinations of SABA + anticholinergic drug (fenoterol + ipratropium bromide; salbutamol+ ipratropium bromide), (5) formoterol, (6) formoterol + ICS (formoterol + beclomethasone; formoterol+ budesonide), (7) salbutamol+ ICS (salbutamol + beclomethasone; salbutamol + budesonide), (8) oral salbutamol.

Anatomical Therapeutic Chemical (ATC) code

(R03AC02) salbutamol

salbutamol

(R03CC02) salbutamol

salbutamol

(R03AK04) salbutamol and ipratropium bromide

salbutamol and ipratropium bromide

(R03AL02) salbutamol and ipratropium bromide

salbutamol and ipratropium bromide

(R03AK13) salbutamol and beclometasone

salbutamol and beclometasone

(R03AK15) salbutamol and budesonide

salbutamol and budesonide

Population studied

Short description of the study population

The study cohort will include all individuals registered in the database between 1st of January 2015 and the most recent available data, with at least 365 days of data visibility prior to becoming eligible for study inclusion. This requirement of at least 365 days of prior data history will not hold for children <1 year of age.

Study design details

Setting

This study will use routinely collected health data from 7 databases in the DARWIN EU® network of data partners from 6 European countries. All databases were previously mapped to the OMOP CDM.

Outcomes

Drugs of interest consisted of reliever therapy, namely: (1) salbutamol inhalation products (administrated using the following devices: dry powder inhalers (DPIs), metered dose inhalers (MDIs), nebuliser solution), (2) Short-acting Beta-2 agonists (SABA) other than salbutamol (terbutaline, fenoterol), (3) short acting anticholinergic drugs (ipratropium bromide, oxitropium bromide), (4) fixed combinations of SABA + anticholinergic drug (fenoterol + ipratropium

bromide; salbutamol+ ipratropium bromide), (5) formoterol, (6) formoterol + ICS (formoterol + beclomethasone; formoterol+ budesonide), (7) salbutamol+ ICS (salbutamol + beclomethasone; salbutamol + budesonide), (8) oral salbutamol.

Summary results

In conclusion, the analysis of prescription rates for inhaled salbutamol and alternatives across European data sources reveals differences in usage patterns across data sources and over years, seasonal variations, and disparities in usage by age, sex, and indications. MDIs were the most prescribed inhalers in IPCI, IQVIA DA, NAJS, and SIDIAP, while DPIs dominated in CPRD-GOLD and DK-DHR, and nebuliser solutions were most prescribed in IMASIS, a hospital data source, especially among young children and the elderly. Asthma was consistently the leading indication for inhaled salbutamol, although prescriptions for LRTI became increasingly common for nebuliser solutions users over time, particularly in IMASIS and SIDIAP. Seasonal peaks in winter were evident across all devices of salbutamol and data sources. Inhaled alternatives, notably formoterol with corticosteroids and short-acting anticholinergics, also showed rising prescription, with patterns that may indirectly reflect the impact of salbutamol availability. These findings underscore the importance of proactive shortage prevention strategies and mitigation efforts to ensure consistent access to essential respiratory treatments, and to better understand how therapeutic alternatives may be leveraged during supply disruptions.

Documents

Study report

DARWIN EU_Report_P3-C1-016_Salbutamol_V5.0.pdf (4.38 MB)

DARWIN EU_Report Supplementary Information_P3-C1-016_Salbutamol_V3.0.pdf (11.14 MB)

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)

Clinical Practice Research Datalink (CPRD) GOLD

Danish Health Data Registries

Institut Municipal d'Assistència Sanitària Information System / Hospital del Mar / PSMAR / (Hospital del Mar Information System)

Integrated Primary Care Information (IPCI)

IQVIA Disease Analyzer Germany

Croatia National Public Health Information System (Nacionalni javnozdravstveni informacijski sustav)

The Information System for Research in Primary Care (SIDIAP)

Use of a Common Data Model (CDM)

CDM mapping

Yes

CDM Mappings

CDM name

OMOP

CDM website

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

CDM version

https://ohdsi.github.io/CommonDataModel/index.html

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

Unknown