DARWIN EU® - Monitoring prescription of essential medicines administered in ICU

First published: 01/04/2025

Last updated: 23/03/2026

Study Finalised

Administrative details

EU PAS number

EUPAS1000000534

Study ID

1000000534

DARWIN EU® study

Yes

Study countries

- Finland
- France
- Greece
- Hungary
- Portugal
- Spain

Study description

The European Medicines Agency (EMA) recently expanded its mandate to include crisis preparedness and management of medicinal products and medical devices, particularly focusing on monitoring and reporting shortages during public health emergencies (PHE).

This extended responsibility encompasses coordinating responses to shortages of critical medical devices and in-vitro diagnostics across European Union (EU) and European Economic Area (EEA) countries.

Recognising the importance of robust scientific and commercial data, there is a growing emphasis on analysing prescriptions of critical medicines in hospital settings, particularly Intensive Care Units (ICUs), to provide valuable insights into usage patterns.

This systematic analysis enhances EMA's ability to proactively monitor and respond quicker to potential public health emergencies, ensuring continued access to essential healthcare resources during crises.

This is a routine repeated study of a population- and patient-level drug utilisation study previously performed within DARWIN EU® (EUPAS1000000089) to report the annual prescription rate of selected medicines of importance for public health emergencies, specifically used in ICU.

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
- Netherlands
- Norway
- Portugal

Spain

Sweden

United Kingdom

First published: 01/02/2024

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Network

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Guido van Leeuwen

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 13/11/2024

Actual: 13/11/2024

Study start date

Planned: 13/11/2024

Actual: 13/11/2024

Date of final study report
Planned: 30/06/2025

Actual: 26/11/2025

Sources of funding

- EMA

Study protocol

DARWIN EU_Protocol_P3-C2-001_RR DUS ICU shortages_V2.pdf (912.87 KB)

DARWIN EU_Protocol_P3-C2-001_RR DUS ICU shortages_V3_Amendment.pdf (962.53 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:

Disease epidemiology

Drug utilisation

Data collection methods:

Secondary use of data

Study design:

•Population-level cohort study (Objective 1). Population-level drug utilisation study of selected medicines of importance for public health emergencies, specifically used in hospital/ICU.

• New drug user cohort (Objectives 2, 3 and 4), Patient-level drug utilisation study regarding characterisation

Main study objective:

1. To estimate the annual proportion of prescribing of selected medicines in a cohort of patients being hospitalised, stratified by ICU admission (yes/no).

2. To characterise the two cohorts of hospitalised patients (ICU admission (yes/no) who initiated treatment with drug of interest in terms of demographics, presence of COVID-19 infection (yes/no), and use of mechanical ventilation (yes/no) at time of first prescribing of drug of interest.

3. To determine the duration of treatment in the cohort of hospitalised patients being treated with drug of interest, stratified by ICU admission (yes/no) and mechanical ventilation (yes/no).

4. To determine the consumption of the specified drugs at hospital level: median cumulative dose per patient, median cumulative dose per hospital and cumulative number of prescriptions as well as median number of prescriptions per patient. Dose will be stratified by route (all/parenteral/non-parenteral/other (including unknown))

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name, other

Ketamine

Propofol

Heparin

Diazepam

Lorazepam

Midazolam

Dexamethasone

Prednisolone

Cisatracurium

Rocuronium

Fentanyl

Remifentanil

Esketamine

Sufentanil

Suxametonium (Succinylcholine)

Atracurium

Anatomical Therapeutic Chemical (ATC) code

(M03AC04) atracurium

atracurium

(M03AC11) cisatracurium

cisatracurium

(H02AB02) dexamethasone

dexamethasone

(N05BA01) diazepam

diazepam

(N01AX14) esketamine

esketamine

(N01AH01) fentanyl

fentanyl

(B01AB01) heparin

heparin

(N01AX03) ketamine

ketamine

(N05BA06) lorazepam

lorazepam

(N05CD08) midazolam

midazolam

(H02AB06) prednisolone

prednisolone

(N01AX10) propofol

propofol

(N01AH06) remifentanil

remifentanil

(M03AC09) rocuronium bromide

rocuronium bromide

(N01AH03) sufentanil

sufentanil

(M03AB01) suxamethonium

suxamethonium

Population studied

Short description of the study population

For population level drug utilisation (Objective 1) study population will include all patients being hospitalised in the respective database, in the study period. The population will be stratified based on ICU admission status (yes/no): those admitted to ICU (ICU cohort) and those hospitalised without ICU admission during their respective hospitalisation (Non-ICU cohort) (Figure 1).
For patient-level drug utilisation (Objective 2 and 3), the study population will include all hospitalised patients who were initiating treatment with selected pre-specified medicines in the study period These patients will be categorised by ICU admission (yes/no) at the time of treatment initiation. This will result in two cohorts: patients who initiate treatment during ICU visit (ICU cohort) and patients who begin treatment during hospital stay outside of ICU, regardless of any prior or subsequent ICU admission during respective hospitalisation (Non-ICU cohort) (Figure 2).

Study design details

Setting

This study was conducted using routinely collected data from 4 data sources in 4 EU countries. All data
sources were previously mapped to the Observational Medical Outcomes

Partnership Common Data Model

(OMOP CDM).

1. Clinical Data Warehouse of Bordeaux University Hospital (CDW Bordeaux), France
2. Papageorgiou General Hospital (PGH), Greece
3. Semmelweis University Clinical Data (SUCD), Hungary
4. Institut Municipal Assistencia Sanitaria Information System (IMASIS), Spain

Documents

Study report

DARWIN EU_Report_P3-C2-001_RR DUS ICU shortages_V3.0.pdf (2.72 MB)

Shiny App

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 Data Warehouse of the Bordeaux University Hospital

Hospital District of Helsinki and Uusimaa patient cohort (FinOMOP)

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

Semmelweis University Clinical Data

Data source(s), other

Papageorgiou General Hospital, Unidade Local de Saúde de Matosinhos, Realtime Database

Data sources (types)

Electronic healthcare records (EHR)

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