DARWIN EU® Monitoring prescription of essential medicines administered in ICU

First published: 27/03/2024

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Study Finalised

Administrative details

EU PAS number

EUPAS1000000089

Study ID

1000000089

DARWIN EU® study

Yes

Study countries

France

Portugal

Spain

Study description

Research question:
What is the annual prescription rate of selected medicines of importance for public health emergencies, specifically used in Intensive Care Unit (ICU)?
Study objectives:
- To estimate annual rate of prescription of selected medicines in a cohort of patients being hospitalized, stratified by Intensive Care Unit (ICU) admission (yes/no).
- To characterize the two cohorts of hospitalized 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).
- To determine dose at treatment initiation and duration of treatment with selected medications in the overall cohort of hospitalized patients being treated with the drug of interest as well as in groups stratified by admission to ICU and mechanical ventilation. Optionally, consumption of the specified drugs at hospital level may be provided.

Study status

Finalised

Research institutions and networks

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

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Network

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Dina Vojinovic

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 12/12/2023

Actual: 12/12/2023

Study start date

Planned: 01/01/2015

Actual: 01/01/2015

Date of final study report

Planned: 15/05/2024

Actual: 13/12/2024

Sources of funding

- EMA

Study protocol

DARWIN_EU_D2.2.3_Protocol_P2-C1-014_DUS of medicines in ICU at risk of shortages_v2.1.pdf (861.84 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:

• 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 (Objective 2 and Objective 3)

Main study objective:

1. To estimate annual rate of prescription of selected medicines in a cohort of patients being hospitalised, stratified by ICU admission (yes/no).
2. To characterize 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).
3. To determine the dose at treatment initiation and duration of treatment with selected medications in the cohort of hospitalised patients being treated with drug of interest, stratified by ICU admission (yes/no) and mechanical ventilation (yes/no). Optionally, consumption of the specified drugs at hospital level may be provided.

Study Design

Non-interventional study design

Cohort

Population studied

Short description of the study population

Population-level drug utilisation: Population-level drug utilisation study included all patients being
hospitalised in the respective databases in the period between 1st of January 2015 and 31st of December 2023
(or the latest date of data availability of respective database, whatever comes first).

Patient-level drug utilisation: Patient-level drug utilisation study included hospitalised patients who were
initiating treatment with selected prespecified medication categorised by ICU admission (yes/no) at the time
of treatment initiation, in the period between 1st of January 2015 and 31st of December 2023 (or the latest
date of data availability of respective database, whatever comes first).

Study design details

Setting

Inpatient setting

Summary results

CONCLUSION

This study provides critical insights into the usage patterns of key medicines during public health emergencies, highlighting differences in ICU and non-ICU settings. The detailed data, including demographic characteristics, prescription rates, and treatment durations, offer valuable information for healthcare planning and resource and medicine allocation.

Documents

Study report

DARWIN EU_Report_P2-C1-014_DUS of medicines in ICU at risk of shortages_V3.pdf (1.85 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 Data Warehouse of the Bordeaux University Hospital

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

Unidade Local de Saúde de Matosinhos

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