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

First published: 01/04/2025

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Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/1000000534

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

Ongoing

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
☐ Hungary
☐ Netherlands
☐ Norway
☐ Portugal
☐ Spain
☐ United Kingdom

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Network

Contact details

Study institution contact

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Primary lead investigator

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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

Sources of funding

- EMA

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 (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

Name of medicine, other

Ketamine

Propofol

Heparin

Diazepam

Lorazepam

Midazolam

Dexamethasone

Prednisolone

Cisatracurium

Rocuronium

Fentanyl

Remifentanil

Esketamine

Sufentanil

Suxametonium (Succinylcholine)

Atracurium

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).

Data management

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

Semmelweis University Clinical Data

Data source(s), other

Papageorgiou General Hospital, Unidade Local de Saúde de Matosinhos

Realtime Database

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