DARWIN EU® Monitoring prescription of essential medicines administered in ICU

First published: 27/03/2024

Last updated: 15/01/2025

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
- [ ] Netherlands
- [ ] Norway
- [ ] Portugal
- [ ] Spain
- [ ] Sweden
- [ ] United Kingdom

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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 type:

Non-interventional study

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

Data sources

Data source(s)

Clinical Data Warehouse of the Bordeaux University Hospital

Institut Municipal d'Assistència Sanitària 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