Retrospective Multi-center Study of the Burden of MBL-producing Enterobacterales in Critically Ill Adults in Spain

First published: 05/01/2026

Last updated: 11/06/2026

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000733

Study ID

1000000733

DARWIN EU® study

No

Study countries

Spain

Study description

This secondary data collection study addresses the significant clinical burden posed by metallo-ß-lactamase (MBL)-producing Enterobacterales in critically ill adult patients. MBL-producing Enterobacterales are characterized by multidrug resistance and present substantial challenges in patient management. The study aims to determine the prevalence of MBL-producing Enterobacterales detected via rectal swabs and clinical specimens among patients in intensive care units (ICU) and hematological departments. The scientific basis for this investigation stems from the insufficient data concerning the relationship between colonization with MBL-producing Enterobacterales and the subsequent development of invasive infections in affected individuals.

Study status

Ongoing

Research institutions and networks

Institutions

Pfizer

First published: 01/02/2024

Last updated: 01/02/2024

Institution

TFS HealthScience (TFS)

Sweden

First published: 01/02/2024

Last updated: 03/04/2024

Institution | Non-Pharmaceutical company | ENCePP partner

Contact details

Study institution contact

Lavinia Popa Lavinia-Maria.Popa@pfizer.com

Study contact

Lavinia-Maria.Popa@pfizer.com

Primary lead investigator

Rafael Cantón

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 14/10/2025

Actual: 14/10/2025

Study start date

Planned: 29/05/2026

Actual: 08/06/2026

Data analysis start date

Planned: 10/08/2026

Date of final study report
Planned: 30/07/2027

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Study protocol

C3601016_NON-INTERVENTIONAL STUDY PROTOCOL_v. 1.0_19NOV2025_Redacted.pdf (394.57 KB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Data collection methods:

Secondary use of data

Study design:

Multi-center, retrospective identification of patients with positive cultures for carbapenemase- and MBL-producing Enterobacterales from surveillance rectal swabs and/or clinical samples.

Main study objective:

To determine the prevalence of carbapenemase- and metallo-beta-lactamase-producing Enterobacterales rectal colonization at admission and during stays in the ICU and Hematology units in the analysis period.

To determine the prevalence and distribution of MBL-producing Enterobacterales infections in critically ill adult patients admitted to ICU and Hematology units in the analysis period.

Study drug and medical condition

Medicinal product name

EMBLAVEO

Study drug International non-proprietary name (INN) or common name

AZTREONAM

AVIBACTAM

Anatomical Therapeutic Chemical (ATC) code

(J01DF51) aztreonam and beta-lactamase inhibitor

aztreonam and beta-lactamase inhibitor

Population studied

Short description of the study population

The study population includes critically ill adult patients admitted to ICU and hematology units in Spain.

Study design details

Setting

ICU and hematology units in Spain.

Outcomes

These variables measure the effect or consequence of the exposure in the study population:

 Prevalence of carbapenemase-producing Enterobacterales colonization: The proportion of patients with positive rectal swabs for CPE, either at admission or during their ICU/hematology stay, calculated by dividing the number of positive

cases by the total number of patients screened within the analysis period.

- Prevalence of MBL-producing Enterobacterales colonization: The proportion of patients with positive rectal swabs for MBL-CPE, either at admission or during their ICU/hematology stay, calculated by dividing the number of positive cases by the total number of patients screened within the analysis period.
- Prevalence of MBL-producing Enterobacterales infection: The proportion of patients who have at least one clinical sample positive for MBL-producing Enterobacterales within 90 days following colonization (counting each unique positive culture), divided by the total number of patients colonized with MBL-producing
Enterobacterales.
- Prevalence of MBL-producing Enterobacterales infection: This refers to the proportion of patients with at least one clinical sample testing positive for MBL producing Enterobacterales within 90 days after colonization (with each unique positive culture counted), divided by the total number of patients screened during the analysis period.
- Distribution of MBL types and resistance patterns: Analysis of resistance profiles, including susceptibility to aztreonam-avibactam, aztreonam, cefiderocol, ceftazidime-avibactam, meropenem, piperacillin-tazobactam, amikacin, colistin, and tigecycline.
- Comparison of prevalence between ICU and hematology patients: Stratified analysis of colonization/infection rates by unit type.

Data analysis plan

The analyses of this study will be mainly descriptive, and as such, no statistical testing will be conducted. Descriptive statistics will be used to determine the prevalence of MBL-CPE colonization and infection, distribution of MBL types, patterns of co-resistance, and comparison of MBL-CPE prevalence between ICU and hematology units.

Documents

Study, other information

C3601016_Annex 2_ENCePP Checklist for Study Protocols_V. 1.0_18NOV2025_for redaction_Redacted.pdf (277.76 KB)

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 sources (types)

Electronic healthcare records (EHR)

Laboratory tests and analyses

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

No

Check completeness

No

Check stability

No

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

No