# Anti-microbial resistance: choice of therapeutic interventions and outcomes for the treatment of infections caused by MDR Gram-negative pathogens

**First published:** 26/10/2017

**Last updated:** 02/07/2024

Study Finalised

## Administrative details

**EU PAS number**

EUPAS21359

**Study ID**

40850

**DARWIN EU® study**

No

**Study countries**

Denmark

France

Greece

Netherlands

Romania

**Study description**

A systematic literature review of all available treatment guidelines and recommendations and the evidence behind them, and a European cross-sectional six-country survey of antibiotic prescribing patterns and algorithms used in clinical practice. As added values, we will include an MDR treatment outcome analysis using existing Danish data and, if accessible, other European individual-level hospital data.

**Study status**

Finalised

# Research institutions and networks

## Institutions

### Aarhus University & Aarhus University Hospital CLINICAL EPIDEMIOLOGY AND DATA SCIENCE, DEPARTMENT OF CLINICAL MEDICINE

Denmark

**First published:** 20/07/2021

**Last updated:** 20/10/2026

**Institution** **Educational Institution**

## Networks

Aarhus University Consortium (ad hoc)

## Contact details


**Study institution contact**

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Study contact

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**Primary lead investigator**

Henrik Toft Sørensen

Primary lead investigator


## Study timelines

**Date when funding contract was signed**

Planned: 17/03/2017

Actual: 17/03/2017

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**Study start date**

Planned: 17/06/2017

Actual: 17/06/2017

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**Date of final study report**

Planned: 17/11/2018

Actual: 12/10/2018

## Sources of funding

- EMA

## Study protocol

Animicrobal resistance.pdf (428.5 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

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**Scope of the study:**

Disease epidemiology

**Data collection methods:**

Combined primary data collection and secondary use of data

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**Main study objective:**

Systematic review of all available treatment guidelines and recommendations and the evidence behind them, and a European cross-sectional six-country survey of antibiotic prescribing patterns and algorithms used in clinical practice. As added value, we will include an MDR treatment outcome analysis using existing Danish data and, if accessible, other European individual-level data.

## Study Design

**Non-interventional study design**

Cohort

Cross-sectional

Systematic review and meta-analysis

## Study drug and medical condition

**Anatomical Therapeutic Chemical (ATC) code**

(J01B) AMPHENICOLS

AMPHENICOLS

## Population studied

**Short description of the study population**

Adult patients, 18 years or older, who had a confirmed multidrug-resistant (MDR) infection and received antimicrobial treatment.

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**Age groups**

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

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**Estimated number of subjects**

1.200.000

# Study design details

**Data analysis plan**

Systematic review of all available treatment guidelines and recommendations and the evidence behind them, and a European cross-sectional six-country survey of antibiotic prescribing patterns and algorithms used in clinical practice. As added value, we will include an MDR treatment outcome analysis using existing Danish data and, if accessible, other European individual-level data.

# Documents

**Study results**

EMA MDR_final study report_revision_without track changes.pdf (1.05 MB)

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**Study publications**

Nørgaard SM, Jensen CS, Aalestrup J, et al. Choice of therapeutic interventions...

# 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)**

Danish registries (access/analysis)

**Data sources (types)**

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

Other

**Data sources (types), other**

Surveys

## Use of a Common Data Model (CDM)

**CDM mapping**

No

## Data quality specifications

**Check conformance**

Unknown

**Check completeness**

Unknown

**Check stability**

Unknown

**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

No