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





## 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 DEPARTMENT OF CLINICAL EPIDEMIOLOGY
☐ Denmark
First published: 20/07/2021
Last updated: 02/04/2024
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

### Study start date

Planned: 17/06/2017 Actual: 17/06/2017

### Date of final study report

Planned: 17/11/2018 Actual: 12/10/2018

# Sources of funding

# 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

Scope of the study:

Disease epidemiology

#### **Data collection methods:**

Combined primary data collection and secondary use of data

#### 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.

#### 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)

#### **Estimated number of subjects**

1200000

## 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)

### 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