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 DEPARTMENT OF CLINICAL EPIDEMIOLOGY

☐ Denmark

First published: 20/07/2021

Last updated: 02/04/2024

Institution **Educational Institution** **ENCePP partner**

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

- 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

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

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