Multi-centre study of the in vitro activity of ceftolozane/tazobactam and other commonly used antibiotics against Pseudomonas aeruginosa isolates from patients in the United Kingdom (INVICTUS)

First published: 20/04/2018

Last updated: 14/03/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS23451

Study ID

23452

DARWIN EU® study

No

Study countries

United Kingdom

Study description

Participating centre will be asked to test a minimum of 50 consecutive clinically significant isolates of P. aeruginosa bacteria. Centres are requested to provide basic background information on the sample and the isolates. All study analysis (re-identification of P. aeruginosa isolates by laboratory testing) and data collection will be performed locally at each participant centre. St. Georges Hospital, London, will act as the designated Central Testing Laboratory where all study isolates will be storage. Additionally, the Central Testing Laboratory will carry out quality control assays in a selected number of isolates per centre. Overall, up to 30% of the isolates included in the study will have been isolated from cystic fibrosis patients.

Study status

Ongoing

Research institutions and networks

Institutions

St George's University of London

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Department of Medical Microbiology

Royal Devon and Exeter NHS Foundation Trust

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Southmead Hospital

First published: 01/02/2024

Last updated: 01/02/2024

Institution | Hospital/Clinic/Other health care facility

Royal Devon and Exeter Hospital Exeter, Freeman Hospital Newcastle, Heart of England Hospital Birmingham, Lewsisham University Hospital and Queen Elizabeth Hospital Lewisham, Pennine Acute Trust Manchester, Barts Health (Royal London & St Bartholamews Hospitals) London, Nottingham (Queen’s Medical Centre) Nottingham, Queen Alexandra Hospital - Cosham Portsmouth, Broomfield Hospital Broomfield, Southmead

Hospital Bristol

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Timothy Planche

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 08/03/2018

Actual: 08/03/2018

Study start date

Planned: 09/03/2018

Actual: 09/03/2018

Date of final study report

Planned: 01/12/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Merck Sharpe and Dohme Ltd

Study protocol

In vitro activity of CT and other antibiotics against P. aeruginosa in the UK FINAL.pdf (2.06 MB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Other study registration identification numbers and links

IRAS Project ID: 241580

Methodological aspects

Study type

Study type list

Study type:

Not applicable

Scope of the study:

Effectiveness study (incl. comparative)

Main study objective:

To evaluate the in vitro activity of ceftolozane/tazobactam and other commonly used antipseudomonal antibiotics against geographically spread P. aeruginosa bacterial isolates in the UK.

Population studied

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

1.400

Study design details

Data analysis plan

This is a descriptive in vitro analysisMethods to Minimize Bias: Consecutive isolates from individual centres will reduce the likelihood of centres picking specific patient or sample types. Sub-group analysis will also help analyse the

characteristics of specific isolates based on antibiogram and sample type. Limitations: The study is a mostly retrospective analysis of unselected stored bacterial isolates from multiple laboratories with heterogeneous patient populations and differing criteria for storing isolates. It is therefore inherently susceptible to selection bias as above. However, it will provide a real-world analysis of clinically significant isolates and allows for sub-group analysis. Inter-laboratory variability in susceptibility testing performance is well established when performing phenotypic analysis of bacterial isolates, results for cystic fibrosis isolates are especially prone to this issue. External quality control will assess any significant variation.

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)

Other

Data sources (types), other

Bacterial isolates are being analysed for antibiotic drug susceptibility.

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