A Real-World Observational Study of Zavicefta® (CAZ-AVI) to Describe the Effectiveness, Safety and Treatment Patterns Among Patients Infected with Complicated Intra-abdominal Infections (cIAI) in China

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Study Planned

Administrative details

EU PAS number

EUPAS48735

Study ID

48736

DARWIN EU® study

No

Study countries

China

Study description

It is a single-arm, multi-center, retrospective, observational study. The study will include hospitalized patients who received CAZ-AVI for the treatment of cIAI between 2019.9.6 (CAZ-AVI commercial launch date in China) and 2022.7.6. The study data will be abstracted from the electronic medical record (EMR), hospital information system (HIS) and laboratory information system (LIS) of several hospitals in China. To ensure good representativeness, hospitals graded as Tertiary A by China government (the highest grade of a three-level hospital classification system in China) from different provinces with large patient pools will be selected. All comers who meet the inclusion/exclusion criteria will be included.

Study status

Planned

Research institutions and networks

Institutions

Sir Run Run Shaw Hospital

First published: 01/02/2024

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Institution

Contact details

Primary lead investigator

Yunsong Yu

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 20/09/2022

Actual: 20/09/2022

Study start date

Planned: 30/09/2022

Data analysis start date

Planned: 31/03/2023

Date of final study report

Planned: 28/09/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

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 type:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Main study objective:

To describe the effectiveness of CAZ-AVI for the treatment of cIAI in terms of clinical response in patients who were exposed to CAZ-AVI for at least 72 hours To describe the safety of CAZ-AVI in terms of drug exposure, in-hospital all-cause mortality, incidence of AEs with explicit attribution to CAZ-AVI To describe the treatment patterns of CAZ-AVI for cIAI patients

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Case-series

Study drug and medical condition

Name of medicine

ZAVICEFTA

Medical condition to be studied

Abdominal infection

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

180

Study design details

Outcomes

in-hospital all-cause mortality, in-hospital cIAI-related mortality, clinical response (categorized as clinical cure, clinical failure and clinical indeterminate). all-cause in-hospital mortality, incidence of AEs and SAEs with explicit attribution to CAZ-AVI, counts of patients with CAZ-AVI exposure in specific scenarios, renal and hepatic function parameters. cIAI infection source control procedure before CAZ-AVI treatment, prior antibiotic therapies, CAZ-AVI dosage, concomitant antibiotic therapy, other antibiotics used/prescribed after CAZ-AVI treatment

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Data analysis plan

All statistical analysis performed will be descriptive. Results will be presented for all patients who meet the eligible criteria. Missing data will not be imputed in this study. Number and percentage of missing data for each variable will be presented but be excluded in the calculation of mean, median and percentage.

Documents

Study results

C3591039 NI Study Report Abstract (Final approval date 15 Sep 2023; Administrative change date 26 Sep 2023)_□□□□□ .pdf(534.13 KB)

Study report

C3591039 NI Study Report (Final approval date 15 Sep 2023; Administrative change date 26 Sep 2023)_□□□□□ .pdf(9.98 MB)

Data management

Data sources

Data sources (types)

Drug dispensing/prescription data

Other

Data sources (types), other

Prescription event monitoring, The study data will be abstracted from the electronic medical record (EMR), hospital information system (HIS) and laboratory information system (LIS) of several hospitals in China.

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