OZAVIE : Prospective observational study in patients treated with Zavicefta® (ceftazidime/avibactam) under real conditions of use

First published: 07/10/2019

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Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/50265

EU PAS number

EUPAS26550

Study ID

50265

DARWIN EU® study

No

Study countries

- [ ] Belgium
- [ ] France
- [ ] Portugal

Study description

ZAVICEFTA® is an association of a 3GC with a new β-lactamase inhibitor and avibactam, which was developed in order to circumvent the main resistance mechanisms to ceftazidime, the major one of which being the production of β-lactamases. Given its spectrum of activity and tolerability, it has raised interest in hospital departments. Phase III studies have enabled the molecule to be registered in its 4 current indications, which are i) complicated intra-abdominal infections (IAIc), ii) complicated urinary tract infections (UTIc), including pyelonephritis, iii) nosocomial pneumonias (NP), including mechanical ventilation-acquired pneumonias (MVAP) and iv) the treatment of infections due to aerobic Gram-negative bacteria in adult patients for whom the treatment options are limited. The aim of this observational study is to collect data on use under actual conditions and tolerability in this specific type of unit, the hospital departments. Primary objective: - To describe the use of ZAVICEFTA® in hospitalised subjects suffering from infection in whom the decision has been taken to treat with ZAVICEFTA®, either alone or in combination. Secondary objectives: - To measure the effectiveness of ZAVICEFTA® at the end of treatment, at 30 days after the start of treatment and at 28 days after the end of treatment - To assess the tolerability of ZAVICEFTA® - To assess in-hospital mortality and hospital readmissions - To assess length of hospital and intensive care unit stay - To define the characteristics of subjects treated with ZAVICEFTA®, particularly their comorbidities, - To describe the sensitivity of pathogens to ZAVICEFTA® and potential alternative therapies to this treatment, - To explain the reason for choosing treatment with ZAVICEFTA®

Study status

Ongoing

Research institutions and networks

Institutions

Pfizer

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Institution

Multiple centres: 55 centres involved in the study

Networks

SPILF

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Philippe Bret

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 27/11/2018

Actual: 26/11/2018

Study start date

Planned: 01/02/2019

Actual: 29/03/2019

Data analysis start date

Planned: 01/05/2020

Date of final study report

Planned: 29/12/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

PFIZER

Regulatory

Was the study required by a regulatory body?

No

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:

Disease epidemiology

Drug utilisation

Effectiveness study (incl. comparative)

Main study objective:

To describe the use of ZAVICEFTA® in hospitalised subjects suffering from infection in whom the decision has been taken to treat with ZAVICEFTA®, either alone or in combination.

Study drug and medical condition

Name of medicine

ZAVICEFTA

Medical condition to be studied

Infectious disease carrier

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

360

Study design details

Outcomes

Measure effectiveness of ZAVICEFTA at EOT, at D30 after the start of treatment and D28 after EOT Assess the tolerability of ZAVICEFTA, in-hospital mortality and hospital readmissions, length of hospital and ICU stay Define characteristics of subjects and their comorbidities Describe sensitivity of pathogens to ZAVICEFTA, potential alternative therapies Explain reason for choosing ZAVICEFTA

Data analysis plan

Appropriate statistical methods (mean values, standard deviations, median values, minimum and maximum values and 95% confidence intervals) will be used to describe the conditions of use for ZAVICEFTA®. In terms of the treatment tolerability assessment, the overall AE rate and rate of AE of specific interest will be expressed, together with their 95% confidence interval. The analysis will consist of a descriptive analysis of all of the variables collected from all of the subjects included in the study (Full Analysis Set – FAS).

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

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