Retrospective Chart Review to evaluate the safety profile of ceftobiprole in patients with impaired hepatic or renal function or immunosuppression (RETRACE)

First published: 08/07/2019

Last updated: 03/01/2024

Study | Finalised

Administrative details

EU PAS number

EUPAS30444

Study ID

48406

DARWIN EU® study

No

Study countries

- ☐ France
- ☐ Germany
- ☐ Italy

Spain

Study description

Post-authorization safety study (PASS), retrospective chart review conducted to characterize the safety profile of ceftobiprole in patients with certain risk factors. Primary aim: To estimate the proportion and relative frequency of treatment-emergent adverse events (TEAEs) with a focus on adverse events of special interest (AESIs) including hepatic disorders, hyponatraemia, acute renal failure, hypersensitivity, pseudomembranous colitis, convulsions and haemolytic disorders in patients with immunosuppression or hepatic impairment or severe renal impairment compared to ceftobiprole - treated patients without these risk factors (control). Secondary aim: To assess the use of ceftobiprole in real-world settings with regards to treatment duration, dosage and safety in “off-label” use.

Study status

Finalised

Research institutions and networks

Institutions

ADVANZ Pharma

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Institution

Contact details

Study institution contact

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Primary lead investigator

Noëlle Jemmely

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 19/03/2019

Actual: 26/06/2019

Study start date

Planned: 09/12/2019

Actual: 30/03/2020

Date of final study report

Planned: 30/01/2024

Actual: 15/11/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

ADVANZ PHARMA Switzerland SARL

Study protocol

Correvio_BPR-PAS-001_Protocol_Version_4.0_20Feb18.pdf(1.17 MB)

Regulatory

Was the study required by a regulatory body?

No

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Main study objective:

The objective of this study is to further characterize the safety profile of ceftobiprole in patients with impaired renal or hepatic function or immuno-suppression.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Retrospective Chart Review

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

CEFTOLOZANE SULFATE

Medical condition to be studied

Renal impairment

Hepatic function abnormal

Immunosuppression

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)

Special population of interest

Renal impaired

Hepatic impaired

Immunocompromised

Estimated number of subjects

422

Study design details

Outcomes

Primary aim: Proportion and relative frequency of Treatment-Emergent AEs in patients treated with ceftobiprole who have at least one of the following conditions: impaired renal (severe) or hepatic function or immunocompromission. The secondary aim is the assessment of ceftobiprole in the naturalistic clinical settings with respect to treatment duration and dosage as well as safety as a result of off-label use (i.e. outside labelled indications).

Data analysis plan

Aim at detection of 2–3-fold increase in frequency of AESIs in patients with risk factors compared to patients without risk factors. Sample size was calculated using a one-sided Z-test at an alpha level of 0.05 and a power of >80% Drop-out rate due to non-evaluability was estimated at 15% Per protocol a total of 422 patient charts had to be reviewed to obtain 360 evaluable charts: 180 charts from patients treated with ceftobiprole without risk factors (control group) 50 charts from patients with severe renal impairment/ ESRD 50 charts

from patients with hepatic impairment 50 charts from immunocompromised patients Proportion of AESIs observed in patients with risk factors is compared to the proportion of AESIs in patients without risk factors from RETRACE (control group) and from pooled phase 3 studies (external control) Related Risk Ratio calculation and comparison

Documents

Study results

Correvio_CO13278_NI-PASS_ABSTRACT Final 1.0 2023 11 15 - short.pdf(118.65 KB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Data source at hospitals are following patient charts depending on availability: admission notes, physician and nurse notes, consultancy reports, discharge summaries, laboratory sheets.

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