A Retrospective Cohort Study of the Risk of Severe Hepatoxicity in Hospitalized patients Treated with Echinocandins

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Study Finalised

Administrative details

EU PAS number

EUPAS14665

Study ID

14666

DARWIN EU® study

No

Study countries

United States

Study status

Finalised

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Weiss Lisa

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 11/12/2013

Actual: 12/03/2014

Study start date

Planned: 15/12/2013

Actual: 24/04/2014

Date of final study report

Planned: 06/04/2015

Actual: 20/04/2015

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Study protocol

Pfizer_Antifungal_Protocol_Oct_09_2013_final.pdf (461.53 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

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Secondary use of data

Main study objective:

The primary objective of the study was to estimate the risk of severe hepatotoxicity associated with exposure to echinocandins, and to compare the risk of severe hepatotoxicity in hospitalized patients treated with anidulafungin to that of hospitalized patients treated with other echinocandins (caspofungin and micafungin) in a real-world setting.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

ECALTA

Medical condition to be studied

Hepatotoxicity

Population studied

Short description of the study population

Patients admitted to a hospital, with ≥ 1 dose of echinocandin antifungal medicines, and aged 18 and above at hospitalization admission.

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

Hepatic impaired

Estimated number of subjects

12678

Study design details

Outcomes

First severe hepatotoxicity event in the observation period. Severe hepatotoxicity was ascertained based on the first LFT of Grades 3, 4, or 5 in the observation period. For this study, the definition of the LFT grades was adapted from the CIT-TCAE, Version 5.0, modified standards from National Cancer Institute, Common Terminology Criteria for Adverse Events.

Data analysis plan

The risks were evaluated in the forms of absolute risk (i.e. cumulative incidence) and incidence rate. The risk ratios were evaluated in the forms of

relative risk and incidence rate ratio.The null hypotheses tested were that the risk of severe hepatotoxicity in hospitalized patients treated with anidulafungin was not statistically different from that in hospitalized patients treated with caspofungin or micafungin.

Documents

Study results

Pfizer Antifungal Safety Study Abstract- April 20, 2016_FINAL.pdf (122.62 KB)

Study report

Pfizer Antifungal Safety Study Report - April 20, 2016_FINAL.pdf (581.09 KB)

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)

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

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