A Multicenter Cohort Study of the Short and Long-term Safety of Micafungin and Other Parenteral Antifungal Agents (MYCOS)

First published: 16/09/2012

Last updated: 01/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS2857

Study ID

35221

DARWIN EU® study

No

Study countries

United States

Study description

This multicenter observational cohort study proposes to establish the risks of short and long-term outcomes in users of parenteral micafungin and in users of other parenteral antifungal agents from 2005 through 2012 with follow-up until 2016.

Study status

Finalised

Research institutions and networks

Institutions

World Health Information Science Consultants, LLC (WHISCON)

Brigham and Women's Hospital and Massachusetts General Hospital MA, USA, Hospital of the University of Pennsylvania PA, USA, University of Pittsburgh Medical Center PA, USA, Duke University Medical Center NC, USA, University of Michigan Hospitals and Health Systems MI, USA, Johns Hopkins University MD, USA

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Sebastian Schneeweiss

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 23/05/2011

Actual: 23/05/2011

Study start date

Planned: 20/09/2012

Actual: 20/09/2012

Data analysis start date

Planned: 01/10/2012

Actual: 01/10/2012

Date of interim report, if expected

Planned: 30/06/2014

Actual: 30/06/2014

Date of final study report

Planned: 30/11/2020

Actual: 05/11/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Astellas Pharma Europe

Study protocol

WHISCON Antifungals Protocol 30 Aug 2011 Amendment 19 July 2012 for ENCEPP posting.pdf (1.12 MB)

9463-cl-1401-clp-05-reissue-v3dot1-en-final-02.pdf (1.95 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 2 (specific obligation of marketing authorisation)

Other study registration identification numbers and links

ISN 9463-CL-1401

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

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:

This multicenter observational cohort study proposes to establish the risks of short and long-term outcomes in users of parenteral micafungin and in users of other parenteral antifungal agents from 2005 through 2012 with follow-up until 2016.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(D01B) ANTIFUNGALS FOR SYSTEMIC USE

ANTIFUNGALS FOR SYSTEMIC USE

Population studied

Short description of the study population

Patients were identified by their first PAF use during a hospitalization between January 1, 2005 and December 31, 2012.

All exclusions were applied to create a single study population for analyses. Patients were excluded if they had earlier recorded PAF use, if they started use of micafungin and a different PAF on the same day, had pre-existing chronic hepatic or renal disease, had both no ALT and no AST or had no bilirubin or had no serum creatinine test results recorded in the 30 days prior to and including PAF initiation. Patients were removed if their last preceding AST or ALT in the 30 days prior to and including PAF initiation were more than five times the local upper limit of normal (ULN), or if their last ALT value was greater than 300 U/L, or if their last AST was greater than 200 U/L, or if their last preceding bilirubin was more than three times the local ULN. Patients were required to have no record of having received dialysis in the 30 days prior to and including cohort entry.

Patients were excluded from the cohort if their last preceding eGFR was <30 ml/min in the 30 days prior to and including PAF initiation. Patients were also

excluded if they had no bilirubin, creatinine, or neither ALT nor AST during follow-up.

Age groups

- Preterm newborn infants (0 – 27 days)
- Term newborn infants (0 – 27 days)
- Infants and toddlers (28 days – 23 months)
- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)
- 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

Immunocompromised

Estimated number of subjects

35.000

Study design details

Outcomes

Three 30-day outcomes (a, b, and c) and one long-term outcome (d) identified during up to 12 years following treatment. a. Treatment-emergent hepatic injury or dysfunctionb. Treatment-emergent renal failure or dysfunctionc. Rehospitalization for the parenteral treatment of fungal infectionsd. Death from hepatocellular carcinoma (HCC)

Data analysis plan

Study outcomes will be identified in the short term (up to 30 days) and the long term (up to 12 years).Survival analysis will compare the occurrence of each 30-day outcome among the parenteral antifungal agents and will employ multivariate propensity score methods to adjust for possible confounding effects of age, gender, race, and comorbid conditions . A further assessment of potential for residual effects due to patient characteristics obtained through chart review of cases and a random sample of the cohort will be conducted. The occurrence of the long-term outcome (HCC mortality) will analogously employ survival analysis and propensity score techniques.

Documents

Study results

9463-cl-1401-clrr-09-disc01-en-final-03.pdf (1.7 MB)

Study publications

Schneeweiss S, Carver PL, Datta K, et al. Short-term risk of liver and renal in...

Schneeweiss S, Carver PL, Datta K, Galar A, Johnson MD, Letourneau AR, Marty F,...

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

Electronic healthcare records (EHR)

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