Non-interventional Study on the Safety and Efficacy for Prevention and Treatment of Fungal Infections in Paediatric Patients in Asia/Oceania – ERADICATE Study

First published: 22/03/2017

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Study Finalised

Administrative details

EU PAS number

EUPAS17838

Study ID

33002

DARWIN EU® study

No

Study countries

- ☐ Australia
- ☐ Hong Kong
- ☐ Indonesia

- [ ] Korea, Republic of
- [ ] Malaysia
- [ ] Singapore
- [ ] Taiwan
- [ ] Thailand

Study description

The aim of the study is to prospectively evaluate the safety and efficacy of micafungin when prescribed for prophylaxis or treatment of fungal infections in different real-world clinical conditions and centers, in pediatric patients in Asia/Oceania.The primary objective of this study is to evaluate the safety of micafungin when prescribed for prophylaxis or treatment of fungal infections in paediatric patients in Asia/Oceania.The secondary objective of this study is to evaluate the efficacy of micafungin in sub-groups of paediatric patients in Asia/Oceania for (1) the prophylaxis of fungal infections, and (2) treatment of proven/probable/possible fungal infections using the European Organization for Research and Treatment of Cancer (EORTC) criteria.

Study status

Finalised

Research institutions and networks

Institutions

Astellas Pharma Global Development, Inc.

Contact details

Study institution contact

Clinical Trial Registration Department
clinicaltrialregistration@astellas.com

Study contact

clinicaltrialregistration@astellas.com

Primary lead investigator

Clinical Trial Registration Department

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 24/12/2016

Study start date

Planned: 30/06/2017

Actual: 21/06/2017

Data analysis start date

Planned: 12/01/2019

Actual: 01/06/2018

Date of final study report

Planned: 29/11/2019

Actual: 25/02/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Astellas Pharma Singapore Pte Ltd

Study protocol

9463-ma-1006-clp-en-final-02 (2).pdf (2.2 MB)

Regulatory

Was the study required by a regulatory body?

No

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

Non-EU RMP only

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

The aim of the study is to prospectively evaluate the safety and efficacy of micafungin when prescribed for prophylaxis or treatment of fungal infections in different real-world clinical conditions and centers, in pediatric patients in Asia/Oceania.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Prescription event monitoring, Prospective Phase 4 study

Study drug and medical condition

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

MICAFUNGIN

Additional medical condition(s)

Post-Exposure Prophylaxis

Population studied

Short description of the study population

Paediatric Asia/Oceania patients diagnosed with proven/probable/possible fungal infections, or requiring prophylaxis for fungal infections, whom have been prescribed with MYCAMINE® 2 mg/kg/day, MYCAMINE® 3 mg/kg/day, MYCAMINE® 100mg/day or MYCAMINE® 150mg/day in a routine clinical practice setting.

Patients will be enrolled in this study only if they meet all of the following criteria:

1. Male or female, aged from birth to <18 years.
2. Prescribed micafungin for prophylaxis or treatment of fungal infections, as determined by treating physician in accordance with the local label.
3. An Informed Consent form has been signed and dated by parents/ guardians (or legally accepted caregivers), consistent with ICH-GCP guidelines and local legislation. An informed assent suitable for the age group has to be obtained from patients if applicable.

Age groups

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

Estimated number of subjects

120

Study design details

Outcomes

Incidence and severity of Adverse Drug Reactions (ADRs) collected during the observational period with onset up to 3 days after end of treatment, with onset later than 3 days after end of treatment and overall. Incidence of Serious Adverse Events (SAE) with onset up to 30 days after end of treatment. Incidence of death attributable to micafungin treatment. Incidence of adverse events. Overall treatment success.Change from baseline to end of treatment in safety laboratory parameters indicating hepatic or renal dysfunction.Adverse events regardless of relationship to micafungin treatment.Mycological response at end of treatment in patients with proven invasive fungal infection with candida or aspergillus species.

Data analysis plan

The study has only one treatment arm. All patients will be treated with Micafungin. Descriptive analyses for baseline characteristics, medication intake and efficacy analyses will in general be stratified in accordance with the clinical presentation of the patients at baseline. For efficacy, results will in addition be presented pooled over the categories probable and proven invasive fungal infection. Safety data will be summarized for the total safety analysis set.In general, all data will be summarized with descriptive statistics (number of patients, mean, SD, minimum, median and maximum) for continuous variables, and frequency and percentage of patients for categorical variables. For efficacy, 95% confidence intervals will be provided.

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)

Electronic healthcare records (EHR)

Other

Data sources (types), other

Prospective patient-based data collection, Prescription event monitoring

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

Unknown