A Non-interventional Post-authorisation Safety Study (PASS) as an Effectiveness Check of the Prescriber Checklist for Mycamine® (micafungin)

First published: 29/03/2021
Last updated: 02/07/2024

Study | Finalised

Administrative details

PURI
https://redirect.ema.europa.eu/resource/50179

EU PAS number
EUPAS35011

Study ID
50179

DARWIN EU® study
No

Study countries
France
Germany
Greece
Netherlands
Poland
Spain
Sweden

Study description
The overall goal of this study was to perform an effectiveness evaluation of the updated Prescriber Checklist (PC) for Mycamine among prescribers of Mycamine. The primary

objectives of the study were to assess prescribers' knowledge levels of: Potential risk of liver tumours associated with Mycamine, and the restricted indication for Mycamine (because of the potential risk of liver tumours, Mycamine should have only been used if other antifungals were not appropriate).

Study status
Finalised

Research institution and networks

Institutions

ICON Commersialisation & Outcomes (MAPI-ICON), ICON

Germany
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Last updated
06/03/2024

Institution

ENCePP partner

Non-Pharmaceutical company

Contact details

Study institution contact
Clinical Trial Registration Department

Study contact

clinicaltrialregistration@astellas.com
Primary lead investigator
Terri Madison

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned:
12/06/2019
Actual:

12/06/2019

Study start date
Planned:
18/05/2021
Actual:
30/06/2021

Date of final study report
Planned:
08/03/2022
Actual:
22/03/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Astellas Pharma Europe B.V.

Study protocol

9463-PV-0002 Protocol v1.2 - Redacted.pdf(1.12 MB)

Regulatory

Was the study required by a regulatory body?
Yes

Is the study required by a Risk Management Plan (RMP)?
EU RMP category 3 (required)

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
Effectiveness study (incl. comparative)
Safety study (incl. comparative)

Data collection methods:
Combined primary and secondary data collection

Main study objective:
The primary objectives were to assess prescribers' knowledge levels of: Potential risk of liver tumours associated with Mycamine, and the restricted indication for Mycamine (because of the potential risk of liver tumours, Mycamine should have only been used if other antifungals were not appropriate).

Study Design

Non-interventional study design
Cross-sectional
Other

Non-interventional study design, other
Multi-national, non-interventional study

Population studied

Short description of the study population
A survey of healthcare professionals who have prescribed Mycamine at least once within 12 months prior to the survey, who practice in any of the participating countries including France, Germany, Greece, Netherlands, Poland, Spain and Sweden.
Inclusion Criteria:
1. HCPs must have prescribed Mycamine within 12 months prior to taking the survey.
2. HCPs must provide permission to share their anonymized responses with the EMA or NCAs

Exclusion Criteria

1. HCPs who participated in the cognitive pre-testing of the survey questionnaire to be used for the study.
2. HCPs who have been direct employees of Astellas, ICON, Syneos, Parexel, GfK, EMA, or an NCA in the participating countries within the past 5 years.

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)

Estimated number of subjects
0

Study design details

Outcomes
-Percentages of HCPs with correct responses to questions regarding: Potential risk of liver tumours associated with Mycamine -Percentages of HCPs with correct responses to questions regarding: the restricted indication for Mycamine (because of the potential risk of liver tumours, Mycamine should have only been used if other antifungals were not appropriate). Percentages of HCPs: -that recall receiving the updated PC -with correct responses to questions regarding: o Hepatic precautions for use o Precaution for use related to haemolytic anaemia/haemolysis in patients with a history of specific conditions o Precaution for use in patients with a history of renal impairment

Data analysis plan
Primary analysis population included HCPs who have completed at least 1 of the primary endpoint survey questions. Descriptive data analyses was conducted for all primary/secondary objectives. Levels of receipt and knowledge was calculated with 95% 2-sided confidence intervals (CI) and was reported overall, by country type (local guideline/standard of care more aligned vs. less aligned with the aRMM regarding restricted indication), and by HCP group. Knowledge related endpoints were analysed by HCP speciality, primary source of information for antifungal treatment selection (ATS), and primary setting/circumstance under which Mycamine is typically prescribed.

Documents

Study results
9463-PV-0002-abstract-disclosure-redacted (1) (1).pdf(227.34 KB)

Data management

Data sources

Data sources (types)
Administrative data (e.g. claims)
Other

Data sources (types), other
HCP surveys

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