Post Marketing Surveillance of Effectiveness (All-Cause Mortality) of Posaconazole Injection and Tablet Treatment of Invasive Aspergillosis in Chinese patients (MK-5592-141)

First published: 18/01/2024

Last updated: 22/07/2025

Study Finalised

Administrative details

EU PAS number

EUPAS108481

Study ID

199010

DARWIN EU® study

No

Study countries

☐ China

Study description

This is a multicenter observational study involving prospective and retrospective data collection from target hospitals using a case report form during the planned recruitment period.

Chinese adult Invasive Aspergillosis (IA) participants who have been treated with posaconazole for at least 7 days in accordance with National Medicinal Products Administration’s (NMPA) approved product information are potential subjects for the study.

Primary Objective: To assess all-cause mortality at Day 42 of IA in Chinese adult participants who receive at least 7 days of posaconazole injection and/or tablet formulations.

Study status

Finalised

Research institutions and networks

Institutions

Merck Sharp & Dohme LLC

United States

First published: 01/02/2024

Last updated: 08/07/2025

Institution **Pharmaceutical company**

10 centres, Merck Investigational Site, China

Contact details

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Primary lead investigator

Clinical Trials Disclosure Merck Sharp & Dohme LLC

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 16/08/2022

Study start date

Actual: 22/09/2023

Data analysis start date

Planned: 27/01/2025

Actual: 24/01/2025

Date of final study report

Planned: 30/06/2025

Actual: 08/07/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Merck Sharp & Dohme LLC

Study protocol

MK-5592-141-00-v1-Protocol_final-redaction.pdf (771.06 KB)

MK-5592-141-01-v1-Protocol_final-redaction.pdf (1.74 MB)

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

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Combined primary data collection and secondary use of data

Study design:

This is a multicenter observational study involving prospective and retrospective data collection from target hospitals using a case report form during the planned recruitment period.
Participants include Chinese adults with IA who have received posaconazole treatment for at least 7 days.

Main study objective:

The aim of this study is to assess all-cause mortality of posaconazole injection and tablet treatment of Invasive Aspergillosis (IA) in Chinese participants by an observational study involving prospective and retrospective data from target hospitals using a case report form during the planned recruitment period.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Multicenter observational study

Study drug and medical condition

Medicinal product name

NOXAFIL

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

POSACONAZOLE

Anatomical Therapeutic Chemical (ATC) code

(J02AC04) posaconazole

posaconazole

Medical condition to be studied

Aspergillus infection

Additional medical condition(s)

Invasive Aspergillosis

Population studied

Short description of the study population

This is a multicenter observational study involving prospective and retrospective data collection from target hospitals using a case report form during the planned recruitment period.
Chinese adult Invasive Aspergillosis (IA) participants (≥18 years old) who have been treated with posaconazole, as an injection and/or tablet formulation, for at least 7 days in accordance with National Medicinal Products Administration’s (NMPA) approved product information are potential subjects for the study.

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)

Estimated number of subjects

55

Study design details

Setting

This is a multicenter observational study involving prospective and retrospective data collection from target hospitals using a case report form during the planned recruitment period.
Participants include Chinese adults with IA who have received posaconazole treatment, as an injection and/or tablet formulation, for at least 7 days.
Relevant patient-level information will be collected from multiple information systems, including electronic medical record (EMR), paper medical records, Hospital Information System (HIS), Laboratory Information System (LIS), and routine patient management material from clinicians in selected hospitals.
Hospitals in which posaconazole injection and/or tablet is available and have the most patients using this product will be considered for inclusion in the study.

Comparators

The study of interest is posaconazole injection and/or tablet formulations treatment administered in a non-interventional setting.
The study will include Chinese adult participants who received posaconazole

injection and/or tablet formulations treatment in routine clinical practice.

Outcomes

To assess all-cause mortality at Day 42 of IA in Chinese adult participants who receive at least 7 days of posaconazole injection and/or tablet formulations.
To assess overall response rate in Chinese adult IA participants and those with disease refractory to amphotericin B, voriconazole, itraconazole or isavuconazole, or other antifungal medications with activity against Aspergillus.
To describe baseline demographics, clinical characteristics and treatment patterns in Chinese adult participants with first line posaconazole treatment or salvage treatment of IA.

Data analysis plan

The primary objective of all-cause mortality will be calculated with 95% confidence interval (CI).
The secondary objectives of overall response rates at the end of posaconazole treatment will be described by percent with 95% CI in the participants with proven or probable IA participants by treatment line.
These analyses will be stratified by data collection method: prospective versus retrospective.
Variables for Demographic and Clinical Characteristics and Treatment Patterns by treatment lines will be described among participants in the study population overall and separately by treatment line.
A descriptive analysis of the distribution of values abstracted for each variable will be provided.
Continuous variables that will be calculated are mean/median, standard deviation (SD), min/max, and interquartile range (IQR, including the first quartile [Q1] and third quartile [Q3]).
The frequency and percentages will be calculated for these variables.

Documents

Study results

MK-5592-P141 CSR_final-redaction.pdf (766.32 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)

Electronic healthcare records (EHR)

Non-interventional study

Other

Data sources (types), other

Prospective patient-based data collection, Electronic Medical Records paper medical records, Hospital Information System (HIS), Laboratory Information System (LIS) routine patient management material

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

No