

# A non comparative , multi centre observational study: Isavuconazole (Cresemba) in Invasive Mould Infections (Invasive Aspergillosis, Invasive Mucormycosis) in India

**First published:** 06/10/2020

**Last updated:** 23/04/2024

Study

Finalised

## Administrative details

### PURI

<https://redirect.ema.europa.eu/resource/48543>

### EU PAS number

EUPAS37495

### Study ID

48543

### DARWIN EU® study

No

## Study countries

☐ India

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## Study description

This is a non-comparative, multi centre, observational study. Adult patients with proven, probable or possible Invasive Aspergillosis or Invasive Mucormycosis as decided by the treating clinician and receiving Isavuconazole (Cresemba) (iv,oral) as per standard of care practices will be recruited from tertiary care centers across India. Outcomes: clinical outcome, microbiological outcomes, length of hospital stay, and discharge status. Key covariates: patient demographics, indication, treatment history, clinical characteristic. Data will be abstracted for patients in the study, from patient charts/ electronic health records after end of six weeks. The data will be recorded in the case report forms (CRFs) for further evaluation. Data will be collected from a maximum of 70 patients with diagnosis of proven, probable or possible IMI, as decided by the treating clinician, during a period of two consecutive calendar years from the protocol approval. The study population will be stratified to achieve a number of study subjects of about 50 Invasive Aspergillosis (IA) and about 20 for Invasive Mucormycosis (IM) on IV and/or oral Cresemba formulations.

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## Study status

Finalised

# Research institutions and networks

## Institutions

Pfizer

**First published:** 01/02/2024

**Last updated:** 01/02/2024

**Institution**

Multiple centres: 5 centres are involved in the study

## Contact details

### Study institution contact

Prithwijit Kundu

**Study contact**

[Prithwijit.Kundu@pfizer.com](mailto:Prithwijit.Kundu@pfizer.com)

### Primary lead investigator

Prithwijit Kundu

**Primary lead investigator**

## Study timelines

### Date when funding contract was signed

Planned: 01/01/2021

Actual: 29/01/2021

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**Study start date**

Planned: 01/10/2021

Actual: 10/01/2022

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**Date of final study report**

Planned: 31/12/2022

Actual: 30/11/2022

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Pfizer

## Study protocol

[C3791010\\_Study Protocol\\_11.09.2020.pdf](#)(390.91 KB)

[C3791010\\_Revised Study Protocol\\_Final\\_Version 5.0.pdf](#)(329.91 KB)

## Regulatory

**Was the study required by a regulatory body?**

Yes

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

Not applicable

## Other study registration identification numbers and links

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Human medicinal product

Disease /health condition

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**Study type:**

Non-interventional study

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**Scope of the study:**

Safety study (incl. comparative)

Other

**If 'other', further details on the scope of the study**

Additional data on post-marketing use of Cresemba in Indian patients

**Data collection methods:**

Secondary use of data

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**Main study objective:**

To describe a case series of patients treated with Isavuconazole (Cresemba) (post approval) for Invasive Mould Infections (Invasive Aspergillosis, Invasive Mucormycosis) in India during a period of two years (post protocol approval)

### Study Design

## **Non-interventional study design**

Other

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## **Non-interventional study design, other**

Single-arm, multicenter, observational study

# Study drug and medical condition

## **Name of medicine**

CRESEMBA

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## **Medical condition to be studied**

Aspergillus infection

Mucormycosis

# Population studied

## **Short description of the study population**

Patients aged 18 years or older diagnosed with invasive aspergillosis/invasive mucormycosis treated with isavuconazole (Cresemba).

Inclusion criteria:

1. Patients 18 years or older
2. Patients with diagnosis of invasive aspergillosis/invasive mucormycosis meeting the criteria for proven, probable or possible invasive mould disease as per the judgement of the treating physician and must have received Cresemba for at least 48h .

Exclusion criteria:

There are no other exclusion criteria for this study.

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### **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)

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### **Special population of interest**

Renal impaired

Hepatic impaired

Immunocompromised

Pregnant women

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### **Estimated number of subjects**

70

## Study design details

### **Data analysis plan**

Descriptive statistics on the study population. Data will be analyzed using standard statistical methods: variables will be described with medians interquartile ranges (IQR), and data analysis will be performed using SPSS software.

## Documents

### **Study results**

[Cresemba NI PASS\\_Summary.pdf](#)(893.79 KB)

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## Data management

## **Data sources (types)**

Other

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## **Data sources (types), other**

Hospital Records

# Use of a Common Data Model (CDM)

## **CDM mapping**

No

# Data quality specifications

## **Check conformance**

Unknown

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## **Check completeness**

Unknown

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## **Check stability**

Unknown

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## **Check logical consistency**

Unknown

# Data characterisation

## **Data characterisation conducted**

No