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

First published: 06/10/2020

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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

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.

Study status

Finalised

Research institutions and networks

Institutions

Pfizer

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Institution

Multiple centres: 5 centres are involved in the study

Contact details

Study institution contact

Prithwijit Kundu

Study contact

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

Study start date
Planned: 01/10/2021

Actual: 10/01/2022

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

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

Not applicable

Other study registration identification numbers and links

C3791010

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

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

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

Non-interventional study design, other

Single-arm, multicenter, observational study

Study drug and medical condition

Name of medicine

CRESEMBA

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.

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)

Special population of interest

Renal impaired

Hepatic impaired

Immunocompromised

Pregnant women

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)

Data management

Data sources (types)

Other

Data sources (types), other

Hospital Records

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