A non-interventional, multicentre, prospective study to estimate the incidence of invasive fungal infections and to monitor the diagnostic and therapeutic management of suspected fungal-related febrile episodes in patients affected with hematological neoplasm (Hema e-Chart II) (MK-0991-803) (Hema E-Chart II)

First published: 14/10/2014

Last updated: 27/02/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/47228

EU PAS number

EUPAS7534

Study ID

47228

DARWIN EU® study

No

Study countries

☐ Italy

Study description

This study will assess the incidence of invasive fungal diseases (IFDs) in patients with hematological malignancies (HMs, acute myeloid leukemia or acute lymphoid leukemia) admitted to Italian hematology wards. This study will also monitor the diagnostic and therapeutic management of suspected fungal-related febrile episodes in patients affected with HMs. Drug use in this study will be based on the investigators' daily clinical practice and data reported on the Summary of Product Characteristics.

Study status

Finalised

Research institutions and networks

Institutions

Merck & Co.

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Azienda Ospedaliero-Universitaria Di Parma

Parma, Italy

Contact details

Study institution contact

Clinical Trials Disclosure Merck Sharp & Dohme LLC

Study contact

ClinicalTrialsDisclosure@merck.com

Primary lead investigator

Clinical Trials Disclosure Merck Sharp & Dohme LLC

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 05/07/2013

Study start date

Planned: 02/03/2015

Actual: 17/02/2015

Data analysis start date
Planned: 11/08/2016

Actual: 21/06/2016

Date of final study report
Planned: 16/06/2017

Actual: 08/06/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Merck Sharpe & Dohme LLC

Regulatory

Was the study required by a regulatory body?

No

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:

Disease epidemiology

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

To estimate the rate of occurrence of possible, probable, and proven IFDs in patients affected by newly diagnosed HMs (acute myeloid leukemia or acute lymphoid leukemia) admitted to hematology wards in Italy.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Observational study, Review of electronic case report forms

Study drug and medical condition

Medical condition to be studied

Fungal infection

Acute myeloid leukaemia

Acute lymphocytic leukaemia

Population studied

Short description of the study population

Patients with hematological malignancies (HMs, acute myeloid leukemia or acute lymphoid leukemia) admitted to Italian hematology wards.

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

Other

Special population of interest, other

Hematological malignancies patients

Estimated number of subjects

1000

Study design details

Outcomes

Rate of occurrence of possible, probable, and proved IFDs.

Data analysis plan

No formal statistical hypotheses will be tested, only descriptive statistics will be calculated. The analysis to assess the outcomes of patients with suspected fungal-related febrile events will be performed using standard survival analysis methods, including Kaplan-Meier product-limit survival curve estimates and log-rank tests for comparison between groups.

Documents

Study results

0991-803 ENCePP.pdf(2.18 MB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

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