A multicenter, prospective, cohort study to investigate the incidence and clinical management of CMV infection in adult patients with hematological malignancies following allogeneic hematopoietic stem cell transplantation in China

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Study Ongoing

Administrative details

EU PAS number

EUPAS45840

Study ID

45841

DARWIN EU® study

No

Study countries

China

Study status

Ongoing

Research institutions and networks

Institutions

The First Affiliated Hospital of Soochow University

First published: 01/02/2024

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Institution

Peking Union Medical College Hospital

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Institution

Peking University People`s Hospital Beijing, southern medical university nanfang hospital Guangzhou, Chinese Academy Of Medical Sciences Peking Union Medical College Tianjin,

ANHUI PROVINCIAL HOSPITAL Anhui, Henan Provincial Cancer Hospital Henan, The First Affiliated Hospital of Zhenzhou University Zhenzhou, Beijing Friendship Hospital, Capital Medical University Beijing, Guangzhou first municipal people's hospital Guangzhou, The Shandong province owned hospital Shandong, The First Affiliated Hospital of Xinjiang Medical University xinjiang

Contact details

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Study contact

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Primary lead investigator

Wu Depei

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 17/11/2020

Study start date
Actual: 13/08/2021

Date of final study report
Planned: 31/12/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

MSD (China) Holding Co., Ltd.

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 type:

Non-interventional study

Scope of the study:

Disease epidemiology

Main study objective:

To determine the incidence of clinically significant CMV infection through Week 24 following allo-HSCT.

Study Design

Non-interventional study design

Cohort

Population studied

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

482

Study design details

Outcomes

Variables to collect for outcomes of interest include clinical outcomes following the allo-HSCT, particularly focusing on the incidence and clinical management for CMV infection.

Data analysis plan

Addressing primary and secondary objectives will be based on descriptive analysis. Subgroup analysis will be performed by pre-specified covariates. Changes of non-confirmatory analyses made after the protocol has been finalized, along with an explanation as to when and why they occurred, will be listed in the clinical study report (CSR) for the study. Post hoc exploratory analyses will be clearly identified in the CSR. The study does not plan to generate any association/casual inference between antiviral drug and CMV infection. The study analysis will not link any safety information to an antiviral drug (including a Merck product) or an antiviral drug class (containing a Merck product). A separate statistical analysis plan (SAP) may be created for this study and finalized before the end of data collection and database lock.

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)

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