# 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


**Study institution 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

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**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)

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**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.

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**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