# Analysis of the Burden of Cytomegalovirus Infection and Disease in Hematopoietic Stem Cell Transplant Recipients

**First published:** 14/06/2018

**Last updated:** 14/03/2024

Study Ongoing

## Administrative details

**EU PAS number**

EUPAS24403

**Study ID**

24404

**DARWIN EU® study**

No

**Study countries**

United Kingdom

**Study description**

This is a singlecentre, retrospective, observational study, in which we will explore the incidence of CMV reactivation and disease in patients undergoing allogeneic stem cell transplantation. We will analyze the dynamics of PCR values and the response to the different treatment options. We will also evaluate the health economics associated with CMV infection in this setting. We will interrogate a database of approximately 350 HSCT patients, that have received stem cell transplantation at the BMT Unit of the Hammersmith Hospital between early 2004 and 2015/2016 (minimum follow-up period of one year). The study is sponsored and funded by Merck Sharp & Dohme Ltd, UK.

**Study status**

Ongoing

# Research institutions and networks

## Institutions

### Imperial College London

United Kingdom

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

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

**Institution** **Educational Institution**

### Blood and marrow transplantation unit

## Networks

# NIHR Medicines for Children Research Network

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

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

Network

## Contact details

### Study institution contact

Darren Cooper darren.cooper@merck.com

Study contact

darren.cooper@merck.com

### Primary lead investigator

Eduardo Olavarria

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 01/10/2017

Actual: 09/10/2017

### Study start date

Planned: 01/12/2017

Actual: 09/12/2017

**Data analysis start date**
Planned: 10/12/2017

Actual: 20/12/2017

**Date of final study report**
Planned: 15/06/2018

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Merck Sharp & Dohme Ltd

## Study protocol

6383 CMV Study Protocol_FINAL signed 191017.pdf (844.41 KB)

## Regulatory

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

No

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

Not applicable

## Other study registration identification numbers and links

REC/HRA reference: 17/LO/1994NIHR CRN Reference: CANC 37047IRAS number: 237860

# Methodological aspects

## Study type

## Study type list

**Study type:**

Non-interventional study

---

**Scope of the study:**

Disease epidemiology

**Main study objective:**

To determine the cumulative incidence of CMV infection and CMV-associated disease in CMV seropositive patients with haematological malignancies, following allogeneic stem cell transplantation at the BMT Unit of the Hammersmith Hospital.

## Study Design

**Non-interventional study design**

Other

---

**Non-interventional study design, other**

Case-series, Database analysis

## Study drug and medical condition

**Medical condition to be studied**

Cytomegalovirus infection

# 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**

350

# Study design details

**Outcomes**

Successful information collection on cumulative incidence of CMV infection and CMV-associated disease in CMV seropositive patients with haematological malignancies, following allogeneic stem cell transplantation at the BMT Unit of the Hammersmith Hospital. To estimate -risks for infection/disease, including associations with patient demographics & treatment characteristics - morbidity/mortality associated with CMV reactivation & serious outcomes - cumulative patient morbidity associated with specific CMV treatments & serious outcomes-PCR values & correlation with response to different CMV-specific treatment-healthcare resource utilization

---

**Data analysis plan**

Demographics will be compared between identified groups (i.e. reactivated vs non-reactivated, etc.) using the Chi-square test or Fisher exact test for categorical variablesand Mann-Whitney U-test for continuous variables. Probabilities of EFS and OS will be estimated from the time of transplantation using Kaplan-Meier estimates. The occurrence of engraftment, acute and chronic GVHD, NRM, and REL will be calculated using cumulative incidence estimates taking into consideration the competing events, inkeeping with EBMT statistical guidelines. Factors with impact in univariate analyses, will be analyzed in multivariate analyses for their association with NRM, REL, EFS, and OS by Cox regression multivariate analyses, using a backward-stepping procedure.

# 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 source(s)**

Hospital Information System

---

**Data sources (types)**

Disease registry

Other

**Data sources (types), other**

The investigator will interrogate a database of approximately 350 HSCT patients, that have received care at Hammersmith between early 2004 and 2015/2016 (minimum follow-up period of one year). This database contains robust data on the recurrence of CMV, as well as complications potentially associated with CMV and the healthcare resource utilizationneeded to treat CMV related complications.

## 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