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

First published: 14/06/2018

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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

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Institution **Educational Institution**

Blood and marrow transplantation unit

Networks

NIHR Medicines for Children Research Network

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Network

Contact details

Study institution contact

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Study contact

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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

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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

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