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Cytomegalovirus (CMV) in solid organ transplant patients

Submission date	Recruitment status	[_] Prospectively registered
29/09/2021	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
25/11/2021	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
24/08/2023	Infections and Infestations	

Plain English summary of protocol

Background and study aims
Cytomegalovirus (CMV) is closely related to the viruses that cause chickenpox and mononucleosis (mono). CMV infections are very common, and most of us will probably have one in our lifetimes.
CMV is one of the most common infections that affect people with a solid organ transplant (SOT). The goal of this study is to describe the treatment patterns and outcomes of CMV in about 400 SOT recipients globally who required treatment for the management of CMV.

Who can participate?
Records from patients that were over 18 years old at the time of the SOT and subsequently were diagnosed with a CMV infection.

What does the study involve?
The study will use the healthcare information that has already been documented from January 1, 2014 (until no later than determined at site level) related to the SOT, CMV infections and outcomes including: hospital visits, clinic visits, written follow-up notes, drug treatments, tests, and procedures. This observational study uses records from routine healthcare. Thus, the results of the study are not expected to be directly or immediately relevant to patient care and will not be shared with each research participant.

What are the possible benefits and risks of participating?
This is a retrospective observational type of study so there are no physical risks that will result from taking part in this study. Taking part in this study has the very low risk of personally identifying information (PII) being accessed by unauthorized people (i.e., individuals who are not part of the study team). To reduce the risk of sharing PII with unauthorized persons, patient identifiers will be removed before being used in research so as to maintain confidentiality and privacy protection. None of the research data will enable identification of individual patients. It is expected there will be limited or no direct or immediate benefit to participants.

Where is the study run from?
Shire Human Genetic Therapies, Inc. a wholly-owned subsidiary of Takeda Pharmaceutical Company Ltd (USA)

When is the study starting and how long is it expected to run for?
May 2019 to December 2021

Who is funding the study?
Shire Human Genetic Therapies, Inc. a wholly-owned subsidiary of Takeda Pharmaceutical Company Ltd (USA)

Who is the main contact?
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Contact information

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Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
287134

Protocol serial number
TAK620-5001, IRAS 287134, CPMS 46421

Study information

Scientific Title
Multinational CMV Outcomes, Treatment Patterns and Healthcare Resource Utilization Study (OTUS) Following Solid Organ Transplant (SOT)

Acronym
OTUS SOT

Study objectives
Primary: Evaluate and describe the clinical outcomes with current management patterns.
Secondary: (1) Describe the treatment patterns of CMV management. (2) Describe the patient / clinical characteristics of transplant patients. (3) Describe the economic burden and healthcare resource utilization of CMV.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/10/2020, Yorkshire & The Humber - Bradford Leeds Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44 (0)207 104 8085; bradfordleeds.rec@hra.nhs.uk), ref: 20/YH/0288

Study design
Multinational non-interventional retrospective study

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Cytomegalovirus infection in transplanted patients

Interventions
The study will use the healthcare information that has already been documented from January 1, 2014 (until no later than determined at site level) related to the SOT, CMV infections and outcomes including: hospital visits, clinic visits, written follow-up notes, drug treatments, tests, and procedures. This observational study uses records from routine healthcare.

Intervention Type
Other

Primary outcome(s)
Patient outcomes measured using patient records:
1. Number of CMV viremia episodes
2. Time to CMV viremia clearance and control
3. Incidence and time to CMV recurrence

4. Incidence of tissue invasive disease, CMV syndrome, graft rejection, graft loss, anti-CMV treatment-related myelosuppression, nephrotoxicity, or CMV resistance
5. Overall survival

Key secondary outcome(s))
Patient outcomes measured using patient records:
1. Frequency of first-, second-and third-line anti-CMV therapies, duration of therapy and time to second-line (or third-line) therapy; time to incident CMV infection and treatment initiation, viral load at time of treatment initiation or switch; medication utilization.
2. Patient pre-transplant characteristics: demographics, transplant indication, viral coinfections, significant comorbidities, underlying immunodeficiencies; Clinical / transplant characteristics; Risk factors for resistant/refractory/intolerant CMV
3. Inpatient/outpatient healthcare utilization; length of hospital stay; diagnostic tests; CMV resistance testing; anti-CMV toxicity management.

Completion date
21/12/2021

Eligibility

Key inclusion criteria
1. Aged ≥18 years at the time of the SOT
2. Received a SOT after January 1, 2014
3. Diagnosed with CMV infection any time after the SOT date
4. Required ≥1 anti-CMV agent to manage CMV infection and were (a) resistant to currently available treatments OR (b) refractory to currently available treatments OR (c) considered intolerant to currently available treatments
5. Follow-up data are available for at least 12 months (1 year) after being characterized in item #4 (above) or until death, whichever occurs first

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
218

Key exclusion criteria
Positive test for HIV before the SOT

Date of first enrolment
23/10/2020

Date of final enrolment
30/11/2021

Locations

Countries of recruitment
United Kingdom

England

France

Germany

Spain

United States of America

Study participating centre
Guy's and St Thomas' NHS Foundation Trust
London
United Kingdom
SE1 7EH

Study participating centre
Hospital Universitario de Bellvitge
Spain
08907

Study participating centre
Hôpital Bretonneau - CHU de Tours
France
37170

Study participating centre
Centre Hospitalier Universitaire de Limoges
France
87000

Study participating centre
University Hospital Essen
Germany
45147

Study participating centre
Hospital Universitari General Vall d'Hebron
Spain
08035

Study participating centre
Johns Hopkins University
United States of America
21287

Study participating centre
University of Pennsylvania
United States of America
19104

Study participating centre
Tufts Medical Center
United States of America
02111

Study participating centre
University of Washington
United States of America
98195-9472

Study participating centre
Weill Cornell Medicine
United States of America
10065

Study participating centre

University Hospital Schleswig-Holstein
Germany
24105

Study participating centre
University Hospital Frankfurt
Germany
60596

Study participating centre
University Hospital Mainz
Germany
55131

Sponsor information

Organisation
Takeda (United States)

ROR
https://ror.org/03bygaq51

Funder(s)

Funder type
Industry

Funder Name
Takeda Pharmaceuticals U.S.A.

Alternative Name(s)
Takeda, Takeda Pharmaceuticals U.S.A., Inc., Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals America, Inc., Takeda in the U.S., Takeda in the United States, Takeda U.S., Takeda Pharmaceuticals North America, Inc., TPUSA

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the study will be made available upon request to researchers who provide a methodologically sound proposal. The data will be provided after its de-identification, in compliance with applicable privacy laws, data protection and requirements for consent and anonymization.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Other unpublished results	Text-based summary of results	30/07/2023	24/08/2023	No	No