

Cytomegalovirus (CMV) in solid organ transplant patients

Submission date 29/09/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 25/11/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 24/08/2023	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data

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

Type(s)

Public

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Type(s)

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

287134

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Secondary study design

Retrospective

Study setting(s)

Hospital

Study type(s)

Other

Participant information sheet

Not applicable (retrospective study)

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 measure

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

Secondary outcome measures

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.

Overall study start date

20/05/2019

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

400

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

England

France

Germany

Spain

United Kingdom

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)

Sponsor details
Takeda Development Centers
95 Hayden Avenue

Lexington, MA
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02421
+1-617-953-7484
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Sponsor type

Industry

Website

<https://www.takeda.com>

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., TPUSA

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

United States of America

Results and Publications

Publication and dissemination plan

The results of this study are intended to be disseminated through publication in peer reviewed scientific journals and other publications (i.e. internal reports).

Intention to publish date

28/02/2023

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	Text-based summary of results		28/06/2023	No	No
Other unpublished results		30/07/2023	24/08/2023	No	No