

Utilising QuantiFERON-CMV to personalise CMV management in haemopoietic stem cell transplant patients

Submission date 13/01/2026	Recruitment status No longer recruiting	☐ Prospectively registered ☒ Protocol
Registration date 15/07/2026	Overall study status Ongoing	☐ Statistical analysis plan ☐ Results
Last Edited 16/07/2026	Condition category Other	☐ Individual participant data ☒ Record updated in last year

Plain English summary of protocol

Background and study aims

Human cytomegalovirus (CMV) is a common virus that can cause severe infections in patients with weakened immune systems, such as those who have undergone a haemopoietic stem cell transplant (HSCT). Patients who have undergone an HSCT are at highest risk of CMV disease between 1 and 3 months after transplant. For this reason, all patients have to take a medication called Letermovir to prevent CMV infection for the first 100 days after their transplant. The aim of this study is to investigate the body's immune response to CMV after transplant using a blood test called QuantiFERON-CMV. This blood test will help us to determine how quickly and how commonly the body's natural immunity to CMV returns after HSCT. It will also give us an understanding of how soon after a HSCT letermovir, used to prevent CMV, can safely be stopped. In addition, we will be investigating whether we can develop a new blood test to investigate for CMV infection (called a whole blood CMV-specific IFN assay). We will also compare how well this new test works compared to the QuantiFERON-CMV (QF-CMV) test and to the gold standard FluoroSpot assay.

Who can participate?

Patients aged 16 years and over who are due to receive an allogenic haemopoietic stem cell transplant at CUH.

What does the study involve?

The study involves assessing in the context of prophylaxis with letermovir, the prevalence of stable CMV-specific T-cell immune reconstitution, defined as two reactive QF-CMV responses at 6 and 8 weeks after HSCT, and measured by the QuantiFERON-CMV ELISA assay (Qiagen). Participants will follow study procedures as outlined in the protocol, including scheduled visits and data collection.

What are the possible benefits and risks of participating?

There is no guarantee that participants will directly benefit from taking part in this study. Information collected as part of their participation in this study may help contribute to the advancement of medical knowledge and potentially improve the management of CMV infection

in HSCT patients.

The risks associated with participating in this study are minimal and are limited to the standard risks associated with having blood drawn, such as discomfort, bruising, or infection at the site of blood collection.

This study has been designed to fit alongside normal patient care and treatment (the standard of care pathway) where possible, but additional clinic visits may need to be scheduled to align with the study sample and data collection time points. Taking part in this study will not disadvantage the participants' standard care in any way.

Where is the study run from?

Addenbrooke's Hospital (UK)

When is the study starting and how long is it expected to run for?

December 2025 to February 2027

Who is funding the study?

Addenbrookes Charitable Trust (ACT) (UK)

Who is the main contact?

Alexandra Azevedo, alex.azevedo@nhs.net

Contact information

Type(s)

Public, Scientific

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Additional identifiers

Integrated Research Application System (IRAS)

318862

Study information

Scientific Title

Utilising QuantiFERON-CMV to personalise CMV management in haemopoietic stem cell transplant patients

Acronym

QuIC

Study objectives

Primary objective:

To determine, in the context of prophylaxis with letermovir, the prevalence of stable CMV-specific T-cell immune reconstitution.

Secondary objectives:

1. Explore the association between stable CMV-specific T-cell immune reconstitution and clinical outcomes (including CMV viraemia, CMV disease, CMV mutation and death) at 12 months
2. Evaluate the cost savings if letermovir is stopped after 8 weeks rather than 100 days in those with stable CMV-specific T-cell immune reconstitution

Exploratory objectives:

1. Develop an in-house whole blood CMV-specific IFN assay that may be transferable to clinical practice
2. Determine the diagnostic accuracy of the in-house whole blood CMV-specific IFN assay compared with the QuantiFERON-CMV ELISA assay (Qiagen) and Fluorospot assay
3. Identify any CMV mutations emerging in the first 52 weeks following allogeneic-HSCTs

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 03/02/2025, Health and Care Research Wales (Floor four, North, Welsh Government Offices, Crown Building, King Edward VII Ave, Cardiff, CF10 3NQ, United Kingdom; +44 (0)29 2023 0457; E. Essex.REC@hra.nhs.uk), ref: 318862

Primary study design

Observational

Secondary study design

Longitudinal study

Study type(s)

Health condition(s) or problem(s) studied

Allogeneic haemopoietic stem cell transplant

Interventions

We plan to recruit 60 evaluable participants who are due to undergo a HSCT at Cambridge University Hospitals NHS Foundation Trust, Addenbrooke's Hospital, and will follow them up over 12 months following their HSCT. Participants will be evaluated at a baseline visit. Follow-up will occur at 6 weeks, 8 weeks, 12 weeks and 12 months post-transplant, during which all participants will have blood samples collected to test for their immune response to CMV. Participants who develop CMV viraemia disease during the course of follow-up will also be asked by the study team to provide residual clinical samples for CMV sequencing. Participants will reach the end of the study once the 12month FU visit is concluded.

Intervention Type

Other

Primary outcome(s)

1. Prevalence of stable CMV-specific T-cell immune reconstitution in the context of Letermovir prophylaxis, defined as two reactive QF-CMV responses, measured using QuantiFERON-CMV ELISA assay at week 6 and 8 post allogeneic-HSCT

Key secondary outcome(s)

1. CMV viraemia, disease, mutation and mortality measured using data collected from SoC results recorded in the medical notes at 52 weeks
2. Cost savings if letermovir is stopped after 8 weeks rather than 100 days in those with stable CMV-specific T-cell immune reconstitution, measured using data collected from SoC results recorded in the medical notes at 6, 8, 12 and 52 weeks follow-ups

Completion date

03/02/2027

Eligibility

Key inclusion criteria

1. Written informed consent form
2. Aged 16 years old or above
3. Due to undergo an allogeneic-HSCT at Cambridge University Hospitals NHS Foundation Trust Addenbrooke's Hospital
4. Confirmed determination of donor AND recipient CMV status by serology
5. Due to take Letermovir prophylaxis following the allogeneic-HSCT
6. Willing and able to comply with scheduled visits, treatment plans, sample collections and other study procedures for the duration of the study

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

16 Years

Upper age limit

100 Years

Sex

All

Total final enrolment

0

Key exclusion criteria

1. Patient is CMV seronegative
2. Patient is in receipt of virus-specific T cell therapy

Date of first enrolment

09/12/2025

Date of final enrolment

03/02/2026

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Addenbrookes

Addenbrookes Hospital

Hills Road

Cambridge

England

CB2 0QQ

Sponsor information

Organisation

Cambridge University Hospitals NHS Foundation Trust

ROR

<https://ror.org/04v54gj93>

Funder(s)

Funder type

Funder Name

Addenbrooke's Charitable Trust, Cambridge University Hospitals

Alternative Name(s)

Addenbrooke's Charitable Trust, Cambridge University Hospitals NHS Foundation Trust, ACT

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.0	17/12/2024	16/07/2026	No	Yes
Protocol file	version 1.1	23/04/2025	16/07/2026	No	No