

QuantiFERON-CMV (QuIC)

PATIENT INFORMATION SHEET & INFORMED CONSENT FORM

Full Study Title: Utilising QuantiFERON-CMV to personalise CMV management in haemopoietic stem cell transplant patients

You are being invited to take part in this research study. Before you decide whether or not you would like to take part, it is important for you to understand why this research is being done and what it will involve.

Please read the following information carefully and talk to others about the study if you wish. Please ask us if anything is not clear or if you would like more information. Please take time to decide whether or not you wish to take part.

Section 1 tells you the purpose of this study and what will happen to you if you participate. Section 2 gives you more detailed information about the conduct of the study.

Section 1: Purpose of the study and what will happen

1. What is the purpose of the study?

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). CMV infection in healthy people can cause mild symptoms such as fever, sore throat and fatigue, but people with weakened immune systems who get CMV can have more serious symptoms affecting their eyes, lungs, liver, oesophagus, stomach and intestines. For this reason, all patients have to take medication to prevent CMV infection for the first 100 days after their transplant. The purpose 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 transplant (HSCT). It will also give us an understanding of how soon after transplant (HSCT) medicines 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 whole blood CMV-specific IFN γ assay). We will also compare how well this new test works compared to the QuantiferON-CMV test and to the gold standard FluoroSpot assay.

We plan to recruit 60 evaluable patients who are due to undergo a haemopoietic stem cell transplant at Cambridge University Hospitals NHS Foundation Trust Addenbrooke's Hospital.

2. Why have I been invited?

You are being invited to participate in this study because you are a patient who is undergoing or has undergone a haemopoietic stem cell transplant at our hospital, and you have been identified as a potential candidate for this study based on your medical condition and history.

3. Do I have to take part?

Taking part in this research study is voluntary. If you decide to take part you will be asked to sign an Informed Consent Form, however you are still free to change your mind and leave the study at any time, without giving a reason. If you choose not to take part, change your participation or to leave the study, your future medical treatment and normal standard of care will not be affected in any way.

4. What will happen to me if I take part?

If you agree to participate in the study, you will be asked to sign the Informed Consent Form at the end of this document and be given a copy of this to take away and refer to later.

If you decide to participate in this study, you will be asked to provide a blood sample at five specific time points before and up to 12 months after your HSCT. The total amount of blood collected at each time point will be approximately 38ml, which is equivalent to just over two tablespoons of blood. The blood sample will be collected by a trained healthcare professional, and the test will be conducted in a laboratory.

The blood samples will be used to run three different blood tests that are used for the detection of CMV. Additionally, if you do develop CMV during the study, we will request a blood sample that has been previously collected as part of your standard of care and held in the pathology laboratory at the hospital, in order to examine the genetic code of the CMV you are infected with.

Wherever possible, study procedures will be arranged to coincide with your usual clinic attendance and blood sampling schedule. If this is not possible, additional study-specific visits may be arranged. Sample collection will be done in the hospital in an appropriate clinical setting.

At each of the five time points during the study, the study team will also access your medical records to collect information relating to your medical history, CMV-related treatments, and clinical outcomes. This information will be used for the purposes of this study only.

Participation in this study is voluntary, and you have the right to withdraw at any time without providing a reason. Your decision to participate or not will not affect your medical care or relationship with your healthcare providers in any way.

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Below is a table showing the sample collection time points:

	Baseline	6 Week post-HSCT Follow-up	8 Week post-HSCT Follow-up	12 Week post-HSCT Follow-up	52 Week post-HSCT Follow-up	CMV Review ^a
Routine blood test results	X	X	X	X	X	X
Research blood sample collection	X	X	X	X	X	
CMV genetic code examination ^a						X

^aIf you develop CMV

You should tell the study team if you feel unwell or different in any way following the study blood collection. If you have any major concerns or are feeling very unwell please contact your study doctor immediately using the contact numbers at the end of this information sheet.

You should discuss your participation in this study with any insurance provider you have (e.g. travel insurance, protection insurance, life insurance, income protection, critical illness cover and private medical insurance) and seek advice if necessary, as failure to notify them may affect or invalidate your cover.

5. What are the possible disadvantages and risks of taking part?

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 your standard care in any way.

6. What are the possible benefits of taking part?

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

7. Are there any expenses or payments for participating?

You will not receive any payment for participating in this study and we are unable to reimburse any expenses incurred by your participation in this study.

This completes Section 1 of the information sheet.

If you are considering participating in the study, please continue to read the additional information in Section 2 before making any decisions.

Section 2: Study Conduct

13. What if new information becomes available?

Sometimes during the course of a study, new information becomes available which might affect your decision to continue participating in this study. Your study doctor will contact you to discuss the new information and whether you wish to continue participating in the study. If you still wish to continue on the study, you may be asked to sign a new Informed Consent Form.

The study Sponsor, the regulatory authority or the study doctor may decide to stop the study at any time. If this happens, we will tell you why the study has been stopped and arrange for appropriate care and treatment for you.

14. What if I decide I no longer wish to participate in the study?

You are free to withdraw from this study at any time without giving a reason and without affecting your future care or medical treatment. No further tests will be performed on you and no further research samples will be collected. Any data or samples already collected or results from tests already performed on you or your samples will continue to be used in the study analysis.

The study doctor may also choose to withdraw you from the study if they feel it is in your best interests or if you have been unable to comply with the requirements of the study. Reasons for stopping or reducing your participation could include:

- You are unable to complete the visits or study documentation as required

15. What if there is a problem?

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. If you have any concerns about any aspect of this study, you should speak to your study doctor who will do their best to answer your questions.

If you wish to complain or have any concerns about any aspect of the way you have been approached or treated during this study, you can also do this through the NHS complaints procedure. In the first instance it may be helpful to contact the Participant Advice and Liaison Service (PALS)) at your hospital, who can advise and direct you to the NHS complaints service as appropriate.

Patient Advice and Liaison Service (PALS) at:

Tel: 01223 216756

Email: cuh.pals@nhs.net

Address: PALS and Complaints Department BOX 53, Cambridge University Hospitals NHS Foundation Trust, Hills Road, Cambridge CB2 0 QQ

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In the event that something does go wrong and you are harmed by taking part in the research that is due to someone's negligence then you may have grounds for a legal action for compensation against Cambridge University Hospitals NHS Foundation Trust or the University of Cambridge. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

The NHS does not provide no-fault compensation, i.e., for non-negligent harm, and NHS bodies are unable to agree in advance to pay compensation for non-negligent harm. They can consider an ex-gratia payment in the case of a claim.

The University has obtained insurance which provides no-fault compensation i.e. for non-negligent harm; you may be entitled to make a claim for this.

16. How will we use information about you?

Cambridge University Hospitals NHS Foundation Trust (CUH) and The University of Cambridge are the Sponsors for this clinical study based in the United Kingdom. They will be using information from you and your medical records in order to undertake this study and will act as the data controller for this study. This means that they are responsible for looking after your information and using it properly. This information will include your name, NHS number, date of birth and contact details. The information provided will be used to do the research or to check your records to make sure that the research is being conducted properly. Only information needed for the research study will be used. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure by:

- Limiting who can access your data so only personnel who have been given permission / authorisation may access it
- Keeping paper copies of your data in locked filing cabinets in restricted access areas
- Keeping your electronic data on secure computers that are password protected

. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

We will keep your study data for a maximum of 5 years. The study data will then be fully anonymized and securely archived or destroyed.

De-identified information about your health and care relevant to this trial may be made available for other research studies run by CUH and/or the University of Cambridge or other organisations. These organisations may be NHS or other public sector organisations, academic institutions, charities and commercial companies in the UK. Making information from

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trials available for further research helps maximise the benefit of conducting trials and allows other researchers to verify results and avoid duplicating research.

We may also share data about you outside the UK for research related purposes to facilitate future research in this therapy area.

If this happens, we will only share the data that is needed. We will also make sure you can't be identified from the data that is shared where possible. This may not be possible under certain circumstances – for instance, if you have a rare illness, it may still be possible to identify you. If your data is shared outside the UK, it will be with the following sorts of organisations: academic institutions, charities and commercial companies.

We will make sure your data is protected. Anyone who may access your data outside the UK must do what we tell them so that your data has a similar level of protection as it does under UK law. We will make sure your data is safe outside the UK by doing the following:

- (some of) the countries your data will be shared with have an adequacy decision in place. This means that we know their laws offer a similar level of protection to data protection laws in the UK
- we need other organisations to have appropriate security measures to protect your data which are consistent with the data security and confidentiality obligations we have. This includes having appropriate measures to protect your data against accidental loss and unauthorised access, use, changes or sharing
- we have procedures in place to deal with any suspected personal data breach. We will tell you and applicable regulators when there has been a breach of your personal data when we legally have to. For further details about UK breach reporting rules visit the Information Commissioner's Office (ICO) website

17. What are your choices about how your information is used if you change or stop your participation in the study?

You can stop your participation in this study at any time, without giving a reason, but we will keep information about you that we have already collected.

We need to manage your records in specific ways for the research to be reliable.

You have the right to ask us to remove, change or delete data we hold about you for the purposes of the study. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.

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18. Where can you find out more about how your information is used?

You can find out more about how we use your information

- At www.hra.nhs.uk/information-about-participants/
- By reading the leaflet available from www.hra.nhs.uk/participantdataandresearch
- Alternatively, please visit, for Cambridge University Hospitals NHS Foundation Trust: <https://www.cuh.nhs.uk/participant-privacy/>
- For University of Cambridge: <https://www.medschl.cam.ac.uk/research/information-governance> or email The Information Governance team at: researchgovernance@medschl.cam.ac.uk
- By asking one of the research team
- By sending an email to cuh.gdpr@nhs.net

19. What will happen to my samples?

If you agree to take part in the research, we will analyse your cells in the blood samples you donate. All samples collected as part of the research will be stored and analysed at suitably regulated facilities.

All samples collected for the study will be labelled with your study ID number which means that the laboratory researchers who are carrying out tests on your samples will not be able to trace them back to you.

It is possible that the residual standard of care samples taken from the hospital Pathology services for CMV sequencing may include patient-identifiable information. This information cannot be removed from pathology samples but will be covered when sent for analysis.

The blood samples collected for the study will be processed and analysed at the hospital. The blood samples will be used to run three different blood tests, which will be conducted by CUH's Department of Immunology and Virology Laboratory.

If you develop CMV during the study, genetic testing will be conducted on blood samples previously collected as part of your standard of care.

At the end of the study, any remaining samples will be retained for use in future research. Future research will only be conducted with appropriate ethical and regulatory approval. Prior to approval, the samples will be stored in a Human Tissue Authority (HTA) licenced facility.

Future research may also involve genetic testing. Samples may be sent to recognised research organisations, including academic and commercial organisations, in the UK and abroad. Samples will not be labelled with any direct identifiers, such as your name or NHS number.

Unless explicitly told otherwise by you, any samples already collected will continue to be used in the study analysis should you decide to withdraw from this study early.

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20. How will results from the study be published?

The results of the study will be anonymous and you will not be able to be identified from any of the data produced. When the study is completed, we will analyse the results and present them at UK or international meetings before they are published in peer reviewed medical journals and used for medical presentations and conferences. They will also be published on a central registry for clinical studies. It could take some years before the results of the study are available. We will prepare a summary of results for people who have participated in the study. You may indicate a preference to have a copy of this summary sent to you. If you are unsure whether you wish to receive this summary, a copy will be sent to your GP to place in your medical records, where it will be accessible at any time.

Anonymous datasets from the study may also be made available to other researchers in line with national and international data transparency initiatives.

21. Who is funding and organising the study?

The study is being funded by a grant from Addenbrooke's Charitable Trust (ACT). The Cambridge Clinical Trials Unit - Cancer Theme will manage the study, and the study is being sponsored by the Cambridge University Hospitals NHS Foundation Trust and The University of Cambridge.

None of the doctors or other staff conducting the study are being paid for, including or looking after participants in the study.

22. Who has reviewed this study?

All research within the NHS is reviewed by an independent group of people called a Research Ethics Committee, to protect your interests. This study has been reviewed by the Addenbrooke's Oncology Research and Development committee and an external independent oncologist. The study has been reviewed and given favourable opinion by (*insert name of REC here*).

23. Further information and contact details

If you have any questions concerning this study, please ask your doctor or research nurse.

Study Doctor:

Name: *[add name]*

Tel: *[add phone number]*

Research Nurse:

Name: *[add name]*

Tel: *[add phone number]*

Thank you for taking the time to read this leaflet and for considering taking part in this study.

CONSENT FORM
QuantiFERON-CMV (QuIC) Study

**Full Study Title: Utilising QuantiFERON-CMV to personalise CMV management in
haemopoietic stem cell transplant patients**

Principal Investigator: Dr Dami Collier

Participant Study Number: _____

Please initial each of the statements below to show that you agree with them.

INITIALS

1	I have read and understood the Participant Information Sheet version 1.0, dated 17/12/2024 for the QuIC study and I confirm that the study procedures and information have been explained to me. I have had the opportunity to ask questions and I am satisfied with the answers and explanations provided.	
2	I understand that my participation in this study is voluntary and that I am free to withdraw at any time, without giving a reason and without my medical care or legal rights being affected, and that any data and samples already collected or tests already performed will continue to be used in the study as described in this information sheet.	
3	I understand that personal information about me will be collected from my hospital records and used in accordance with this information sheet. This information will be kept in the strictest confidence. I will not be identifiable in any results published.	
4	I understand that research personnel, responsible individuals from the Sponsor and regulatory authorities may look at sections of my medical notes or information related directly to my participation in this study where it is relevant to my taking part in research and that they will keep my personal information confidential. I give permission for these individuals to have access to my records.	
6	I understand that de-identified information collected about me may be used to support other research in the future, including research conducted by both commercial and non-commercial organisations in the UK and abroad.	
7	I understand that my GP will be informed of my participation in this study and sent details of the QuIC study.	
8	I have read and understood that there is no compensation for participation in this study as specified in the Participant Information Sheet.	
9	I understand that the doctors in charge of this study may close the study, or stop my participation in it at any time without my consent.	
10	I have read and understood my responsibilities for the trial as listed in section 4.	

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11	I agree to give blood samples during this study for research purposes related to this study.	
12	I give consent to be contacted by telephone by the research team.	
13	I agree to participate in the QulC research study.	

OPTIONAL If an optional clause is left blank/not initialled we will consider this to mean you have declined consent		INITIALS
		YES
14	I understand that my samples may be retained for future research with appropriate regulatory and ethical approval. Samples may be sent to organisations, including commercial organisations, in the UK and abroad.	
15	I wish to be informed of the research findings once they are available. Please send a copy of the study findings to me and/or my family.	

I agree to participate in this study:

..... Name of Patient (to be completed by patient)	 Date (to be completed by patient)	 Signature
..... Name of Research Staff Member taking consent	 Date	 Signature
..... Name of Witness to consent (if applicable)	 Date	 Signature

Witness consent is only to be used as detailed in the study protocol.

Time of Consent (24hr clock) _____:_____

1 copy to the patient, 1 copy to be placed in the hospital notes, 1 (original) in the Investigator site file