HKU Med LKS Faculty of Medicine
Department of Ophthalmology
香港大學眼科學系

Department of Ophthalmology, Li Ka Shing Faculty of Medicine, The University of Hong Kong

Ocular Graft-Versus-Host-Disease Following Allogeneic Haematopoietic Stem Cell Transplantation: a Territory-wide Prospective Cohort

Participant Information Sheet and Informed Consent Form

2021/12/9

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Participant Information Sheet

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Principal Investigator: Dr Allie Lee

Introduction

The Department of Ophthalmology, LKS Faculty of Medicine, the University of Hong Kong is conducting a study titled 'Ocular Graft-Versus-Host-Disease (oGVHD) Following Allogeneic Haematopoietic Stem Cell Transplantation (HSCT), a Territory-wide Prospective Cohort' (this study). Patients attending the pre-HSCT assessment clinic at Queen Mary Hospital (QMH) will be invited to join the study. The study aims to identify early diagnostic markers and investigate the natural history and epidemiology of oGVHD. You are cordially invited to join this study.

Ocular manifestations occur in up to 90% of HSCT recipients affected by chronic GVHD, resulting in debilitating ocular surface diseases, visual loss and reduced quality of life. However, current understanding in epidemiology and diagnosis of oGVHD remains limited. In collaboration with the Department of Haematology of QMH, this study sets out to establish a territory-wide prospective cohort of patients who receive allogeneic HSCT to fill the knowledge gap.

Please peruse this information sheet and ask any questions you may have about this study. The research team will answer your questions. You may consult your family members, friends or family doctor if necessary. If you have any questions or would like to receive more information, please consult the investigators and decide afterwards. You will also be given a signed copy of the informed consent form and participant information sheet for retention.

Purpose of research

To investigate the epidemiology and enhance diagnosis in oGVHD.

Description of study design and procedures

This is a prospective observational study. Patients will be invited for assessment at baseline within one month prior to HSCT, and at months 3, 6, 9, 12 after HSCT, with an optional extension to 18 and 24 months, and annually up to 5 years.

During each visit, a comprehensive eye examination will be performed by an ophthalmologist experienced in oGVHD. Symptom questionnaires, tear film parameters, imaging of the ocular surface and anterior segment will also be carried out. Tear and conjunctival swab samples will be collected in some visits.

One accompanying family member of the patients will also be recruited as the family control. Family control subjects will receive eye assessments performed by an ophthalmologist. Microbiome and tear samples will be collected for comparison. The schedule of assessment and collection is the same as the corresponding post-HSCT case.

Potential benefits
Participants will be closely monitored for any emerging sign of oGVHD. Participants could seek medical attention in no time if any clinical manifestation of oGVHD started to appear. Participants will help the society by contributing to the medical research of oGVHD.

Potential risks or discomfort
Participating in this study will not increase potential risks. Conjunctival swab and tear collection may cause very mild discomfort. These sample collection methods are widely used worldwide and in general very well tolerated.

Costs and rewards of the study
Participants will not be charged an extra fee for participating in this study.

Alternative treatments if participant opts out of the study
The participant will continue to receive routine care if they opt not to join the study.

Expected research period
You will be in the study for up to about 5 years.

Circumstances under which your participation in the research will be terminated
We reserve the right to terminate your participation in the research project. If any safety concerns are raised during the study, interim results from the study showed no additional samples are needed, or you are not available to attend follow-up visits, you will be informed your participation will no longer be required.

Arrangements after completion of study
After study completion, your care will be handed back to the public hospitals as required.

Compensation and treatment available for study-related injury
If you are injured during your participation in this study, the investigator will provide medical treatment or refer you to other treatment. You are not giving up any of your legal rights by signing this informed consent form.

Confidentiality
The research team will have access to your medical records. Electronic data will be only saved in physically-secured and password-protected computers in our research office. All the information collected is for research purposes only and will be kept strictly confidential. None of your information will not be disclosed to any third party without your consent. We will keep your information (including your medical record information) confidential to the extent permitted by laws and/or regulations, and will not make it public. If the research team needs to publish or submit the study results in scientific meetings or journals, your name and identifying information will not be disclosed. If necessary, each participant has their right to acquire their personal data and the publicly reported results. Records and results of all study investigations can be destroyed on your request in future.

By signing a written informed consent form, you are authorizing the Research Ethics Committee (REC) and the regulatory authority(ies) a direct access to your original research records for verification of clinical trial procedures and/or data, without violating your confidentiality, to the extent permitted by the applicable laws and regulations. Personal data will be kept for 5 years after study completion.

Under the laws of Hong Kong (in particular the Personal Data (Privacy) Ordinance, Cap 486),

you enjoy or may enjoy rights for the protection of the confidentiality of your personal data, such as those regarding the collection, custody, retention, management, control, use (including analysis or comparison), transfer in or out of Hong Kong, non-disclosure, erasure and/or in any way dealing with or disposing of any of your personal data in or for this study. For any query, you should consult the Privacy Commissioner for Personal Data or their officer (Tel no.: 2827 2827) as to the proper monitoring or supervision of your personal data protection so that your full awareness and understanding of the significance of compliance with the law governing privacy data is assured.

Voluntary participation / Withdrawal /

Your participation in this study is entirely voluntary. You will be updated of new information that may be relevant to your willingness to continue participation in the study. You are allowed as much time as you need to consider participation in this study, or to discuss with your relatives prior to signing the informed consent form. You can call us via the contact telephone number provided on this participant information sheet when you need help making your decision. You have the right to refuse participation or to withdraw from this study at any time, with no prejudice towards your present or future medical treatments at the Chinese University of Hong Kong or any of the hospitals involved. After signing the Informed Consent Form, a Participant Information Sheet and a copy of signed Informed Consent Form will be given. Even after signing the informed consent form, you are free to withdraw your consent and discontinue your participation in the study at any time. Once you request to withdraw, all clinical data arising from study investigations will be deleted. The clinical data in the medical records will, however, be retained for future clinical management.

Further information

For further information, you can contact us at the address and telephone below.

Investigator: Dr Allie Lee
Telephone no.: 3962 1405
Address: Department of Ophthalmology, The University of Hong Kong
Room 301, Block B, Cyberport 4, 100 Cyberport Road, Hong Kong

If you have any questions about your rights as a subject, you may contact the Institutional Review Board of The University of Hong Kong/Hospital Authority Hong Kong West Cluster (HKU/HA HKW IRB).

Telephone no.: 2255 4086
Address: Room 901, 9/F, Administration Block, Queen Mary Hospital,
102 Pokfulam Road, Hong Kong

Department of Ophthalmology,
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Informed Consent Form

*Please tick the appropriate box.

☐HSCT Recipient /☐Family control

I _____hereby consent to participate in the research study of **"Ocular Graft-Versus-Host-Disease Following Allogeneic Haematopoietic Stem Cell Transplantation: a Territory-wide Prospective Cohort.**

I have read the **PARTICIPANT INFORMATION SHEET** and **INFORMED CONSENT FORM**. The study has been explained to me. I understood all the benefits and the risks associated with this study. I am not giving up any of my legal rights by signing this form. I have had opportunities to ask questions and all my questions have been satisfactorily answered. I have received enough information about the study.

If the result of my participation in this study caused any physical injury or emotional disturbance, the investigator will treat me or refer me to treatment.

By signing this informed consent form, I certify that all information provided is true and correct. I consent to participate in this study and understand that my participation is voluntary and I have the right to withdraw at any time without having to give a reason for withdrawing and the withdrawal will not affect my present and future medical care.

I *☐agree / *☐disagree to be contacted via phone or email to inquire about my interest in participating relevant studies in future.

I understand that my identity will be kept confidential. I agree to authorize the Research Ethics Committee (REC) and the regulatory authority(ies) a direct access to my original medical records for verification of clinical trial procedures and/or data, without violating my confidentiality, to the extent permitted by the applicable laws and regulations.

Name of participant (in BLOCK letters)	Signature	Date
Name of investigator (in BLOCK letters)	Signature	Date

I will be given a copy of the Participant Information Sheet and a signed copy of this Informed Consent Form.