SingHealth

PARTICIPANT INFORMATION SHEET AND CONSENT FORM

You are being invited to participate in a research study.

Before you take part in this research study, the study must be explained to you and you must be given the chance to ask questions. Please read carefully the information provided here. If you agree to participate, please sign the consent form. You will be given a copy of this document to take home with you.

STUDY INFORMATION

Protocol Title:

Evaluation of the Efficacy of Descemet Membrane Transplantation for the Treatment of Fuchs' Endothelial Dystrophy

Principal Investigator:

A/Prof Jodhbir S Mehta

Cornea and External Eye Disease

Singapore National Eye Centre

11 Third Hospital Avenue, #08-00, Singapore 168751

Phone number: 62277225

PURPOSE OF THE RESEARCH STUDY

You are being invited to participate in a research study of Descemet Membrane transplantation for the treatment of Fuchs' Endothelial Dystrophy (FED). We hope to learn if Descemet Membrane transplantation may be an effective alternative to endothelial keratoplasty for the treatment of FED. You were selected as a possible participant in this study because you are currently suffering from FED which has not responded favourably to conservative management, and would require surgical intervention.

This study will recruit 20 participants from the Singapore National Eye Centre over a period of 1 year starting from July 2016.

Any samples of tissues, blood and/or body fluids obtained during the course of this study will be stored and analysed only for the purposes of this study for a period not exceeding 15 years, and will be destroyed after completion of the study.

When your participation in the study ends, you will no longer have access to the surgical intervention of Descemet Membrane transplantation, unless special additional arrangements are made by the Principal Investigator.

STUDY PROCEDURES AND VISIT SCHEDULE

If you agree to take part in this study, you will be asked to undergo Descemet Membrane transplantation for treatment of FED. Your participation in the study will last 12 months. You will undergo Descemet Membrane transplantation once at the start of the study protocol, and be followed up for a minimum of 12 months following the procedure. You will need to visit the doctor's office 8 times following the procedure during the course of the study. This is no more than for standard endothelial keratoplasty patients at our centre. At each review visit you will have a series of investigations carried out in order to assess your vision and the shape of your cornea. All these investigations are not invasive and therefore do not cause any discomfort or put your eye at risk. The majority of the investigations are standard, and are eye examinations carried out routinely in SNEC. During the first visit prior to surgery, 10mls of blood (2 tablespoons) will be obtained for genetic analysis, after which no further blood-taking will be necessary. Clinical data, ophthalmic imaging data and biological samples may be used for future research.

Schedule of visits and procedures:

Visit 1: Before surgery

Visit 2: Surgery

Visit 3: First day following surgery

Visit 4, 5, 6, 7, 8: Weeks 1, 3, 6, 12, 24

Final Visit: Week 48

Additional clinic visits may be scheduled by the principal investigator, as deemed medically necessary.

YOUR RESPONSIBILITIES IN THIS STUDY

If you agree to participate in this study, you should:

- Keep your study appointments. If it is necessary to miss an appointment, please contact the study staff to reschedule as soon as you know you will miss the appointment.
- Inform the Principal Investigator as soon as possible about any side effects that you may have encountered.
- Be prepared to visit the hospital at least 8 times following the surgery, and undergo all the procedures that are outlined above.

WITHDRAWAL FROM STUDY

You are free to withdraw your consent and discontinue your participation at any time without prejudice to you or effect on your medical care. If you decide to stop taking part in this study, you should tell the Principal Investigator.

If you withdraw from the study for any reason, prior to undergoing the surgical procedure of Descemet Membrane Transplantation, you will continue to receive standard medical and surgical care for your condition of Fuchs' Endothelial dystrophy, as offered to all patients seen in the Singapore National Eye Centre

If you withdraw from the study for any reason, following the surgical procedure of Descemet Membrane Transplantation, you will be strongly encouraged to continue to attend follow-up consultations at the Singapore National Eye Centre, at a frequency deemed appropriate by the principal investigator, in view of safety considerations

If you withdraw from the study due to the development of a complication, we will continue to provide appropriate care for the complication and the underlying medical condition of Fuchs' Endothelial Dystrophy, until your medical condition stabilizes.

All data that have been collected until the time of your withdrawal will be kept and analysed. The reason is to enable a complete and comprehensive evaluation of the study.

The biological samples collected for the study will be deemed to be given to the Singapore Eye Research Institute and will not be returned to you. However, you retain your right to ask the Principal Investigator to discard or destroy any remaining samples if they have not been anonymised.

Your doctor, the Principal Investigator and/or the Sponsor of this study may stop your participation in the study at any time for one or more of the following reasons*:*

- Failure to follow the instructions of the Principal Investigator and/or study staff.
- The Principal Investigator decides that continuing your participation could be harmful.
- You need treatment not allowed in the study.
- The study is cancelled.

WHAT IS NOT STANDARD CARE OR EXPERIMENTAL IN THIS STUDY

The study is being conducted because Descemet Membrane Transplantation is not yet proven to be a standard treatment in participants with Fuchs' Endothelial Dystrophy. We hope that your participation will help us to determine whether Descemet Membrane Transplantation is equal or superior to Endothelial Keratoplasty for the management of Fuchs' Endothelial Dystrophy.

POSSIBLE RISKS, DISCOMFORTS AND INCONVENIENCES

- Post-surgical recovery of visual acuity may take longer than usually encountered following Endothelial Keratoplasty (i.e. longer than 6 weeks).
- In the event that Descemet Membrane Transplantation fails to adequately treat your condition within 6 weeks, you may have to undergo Endothelial Keratoplasty, which is an additional surgical procedure.
- Besides prolonged recovery as mentioned above, the risk profile for Descemet Membrane Transplantation is expected to similar to that of standard Endothelial Keratoplasty. Potentially blinding complications may occur but are considered rare (less than 5%), and they include conditions such as (but are not limited to): graft dislocation/detachment, gas-bubble induced pupillary block, fluctuations in intraocular pressure, intraocular inflammation, intraocular infections, intraocular hemorrhage, retinal tears and retinal detachment (non-exhaustive list).
- Additionally, Descemet Membrane Transplantation may involve risks which are currently unforeseeable.
- Venipuncture will also be performed to obtain 10mls of blood for genetic testing. The

procedure may result in transient, mild discomfort.

POTENTIAL BENEFITS

There is no assurance you will benefit from this study. However, your participation may contribute to the medical knowledge about the efficacy of Descemet Membrane Transplantation for the treatment of Fuchs' Endothelial Dystrophy.

Should Descemet Membrane Transplantation be found to be effective for the treatment of Fuchs' Endothelial Dystrophy, you would avoid having to undergo standard Endothelial Keratoplasty. This eliminates the requirement for long term use of topical steroidal eyedrops which is necessary in patients who have undergone Endothelial Keratoplasty. The use of a decellularized Descemet Membrane for transplantation (as opposed to a cellular endothelial graft) may also carry lower risks of graft rejection and the need for repeat surgical interventions in future.

ALTERNATIVES

If you choose not to take part in this study, the alternative is to have what is considered standard care for your condition. In our institution this would be Endothelial Keratoplasty in the form of Descemet Stripping Automated Endothelial Keratoplasty.

IMPORTANT INFORMATION FOR WOMEN PARTICIPANT

The effects of peri-pregnancy intraocular surgery and the use of therapeutic / anaesthetic agents on a baby's development are not known. Therefore, pregnant and breast-feeding women may not take part in this study. Women who have a chance of becoming pregnant must have a negative pregnancy test at study entry and use birth control during the study.

PARTICIPANT'S RIGHTS

Your participation in this study is entirely voluntary. Your questions will be answered clearly and to your satisfaction.

In the event of any new information becoming available that may be relevant to your willingness to continue in this study, you or your legal representative will be informed in a timely manner by the Principal Investigator or his/her representative.

By signing and participating in the study, you do not waive any of your legal rights to revoke your consent and withdraw from the study at any time.

CONFIDENTIALITY OF STUDY AND MEDICAL RECORDS

Information collected for this study will be kept confidential. Your records, to the extent of the applicable laws and regulations, will not be made publicly available. Only your Investigator(s) will have access to the confidential information being collected.

However, the Singapore National Eye Centre, Singapore Eye Research Institute, Regulatory Agencies, Institutional Review Board and Ministry of Health will be granted direct access to your original medical records to check study procedures and data, without making any of

your information public.

By signing the Consent Form, you consent to (i) the collection, access to, use and storage of your Personal Data by the Singapore National Eye Centre and (ii) the disclosure of such Personal Data to our authorised service providers and relevant third parties for the purpose of future research studies ("Future Studies"). Specifically, bio-specimens, ophthalmic imaging data and other relevant clinical information pertinent to your medical condition of Fuchs' Endothelial Dystrophy and surgical intervention of Descemet Membrane Transplantation may be de-identified and used in future research studies.

Where required, such Future Studies will be submitted for review and necessary approval by the relevant institutional review board.

"Personal Data" means data about you which makes you identifiable (i) from such data or (ii) from that data and other information which an organisation has or likely to have access. Examples of personal data include medical conditions, medications, investigations and treatment history.

By signing the Consent Form, you also confirm that you have read, understood and consented to the SingHealth Data Protection Policy, the full version of which is available at www.singhealth.com.sg/pdpa.

Data collected and entered into the patient's clinical dossier are the property of the Singapore National Eye Centre and Singapore Eye Research Institute. In the event of any publication regarding this study, your identity will remain confidential.

COSTS OF PARTICIPATION

If you take part in this study, the following will be performed at no charge to you: Descemet Membrane Transplantation.

If you take part in this study, you will have to pay for the following: Endothelial Keratoplasty (should there be prolonged visual recovery following Descemet Membrane Transplantation), cataract extraction surgery (if necessary), all eyedrops, all medical consultations and all ophthalmic investigations.

There will be no further financial reimbursement offered to you for this study.

RESEARCH RELATED INJURY AND COMPENSATION

The Hospital does not make any provisions to compensate study participants for research related injury. However, compensation may be considered on a case-by-case basis for unexpected injuries due to non-negligent causes.

By signing the Consent Form, you will not waive any of your legal rights or release the parties involved in this study from liability for negligence.

WHO TO CONTACT IF YOU HAVE QUESTIONS REGARDING THE STUDY

If you have questions about this research study or in the case of any injuries during the course of this study, you may contact the Principal Investigator Principal Investigator A/Prof Jod Mehta, Cornea and External Eye Disease, Singapore National Eye Centre, 11 Third

Hospital Avenue, #08-00, Singapore 168751. The contact phone number is 63228378.

WHO HAS REVIEWED THE STUDY

This study has been reviewed by the SingHealth Centralised Institutional Review Board for ethics approval.

If you have questions about your rights as a participant, you can call the SingHealth Centralised Institutional Review Board at 6323 7515 during office hours (8:30 am to 5:30pm).

If you have any complaints about this research study, you may contact the Principal Investigator or the SingHealth Centralised Institutional Review Board.

CONSENT FORM

Details of Research Study

Protocol Title:

Evaluation of the Efficacy of Descemet Membrane Transplantation for the Treatment of Fuchs' Endothelial Dystrophy

Principal Investigator:

A/Prof Jod Mehta

Cornea and External Eye Disease, Singapore National Eye Centre, 11 Third Hospital Avenue, #08-00, Singapore 168751.

Contact phone number is 63228378 or 62277225.

Participant's Particulars

Name: NRIC No.:

Address:

Sex: Female/Male Date of birth _____
dd/mm/yyyy

Race: Chinese/ Malay/ Indian /Others (please specify) _____

I agree to participate in the research study as described and on the terms set out in the Participant Information Sheet.

I have fully discussed and understood the purpose and procedures of this study. I have been given the Participant Information Sheet and the opportunity to ask questions about this study and have received satisfactory answers and information.

I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reasons and without my medical care being affected.

By participating in this research study, I confirm that I have read, understood and consent to the SingHealth Data Protection Policy. I also consent to the use of my Personal Data for Future Research.

I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reasons and without my medical care being affected.

O I agree to allow my bio specimens / eye images / data collected* during the course of this study to be used for the purposes of related research arising in the future.

O I disagree to allow my bio specimens / eye images / data collected* during the course of this study to be used for the purposes of related research arising in the future.

**delete where appropriate*

Name of participant	Signature/Thumbprint (Right / Left)	Date of signing
_____	_____	_____

To be filled by parent / legal guardian / legal representative, where applicable

I hereby give consent for the above participant to participate in the proposed research study. The nature, risks and benefits of the study have been explained clearly to me and I fully understand them.

I confirm that I have read, understood and consent to the SingHealth Data Protection Policy. I also consent to the use of the participant's Personal Data for Future Research.

Name of participant's parent /legal guardian	Signature	Date of signing
_____	_____	_____

To be filled by translator, if required

The study has been explained to the participant/ legal representative in

_____ by _____.
Language Name of translator

To be filled witness, where applicable

An impartial witness should be present during the entire informed consent discussion if a participant or the participant's legal representative is unable to read. After the written consent form and any written information to be provided to participant, is read and explained to the participant or the participant's legal representative, and after the participant or the participant's legal representative has orally consented to the participant's participation in the study and, if capable of doing so, has signed and personally dated the consent form, the witness should sign and personally date the consent form.

Witnessed by: _____ _____
Name of witness Designation of witness

_____ _____
Signature of witness Date of signing

Investigator's Statement

I, the undersigned, certify to the best of my knowledge that the participant/participant's legal representative signing this consent form had the study fully explained and clearly understands the nature, risks and benefits of his/ her/ his ward's/ her ward's participation in the study.

_____ _____ _____
Name of Investigator Signature Date