Patient Information Sheet

Research Title:

DETECT-PD – Dialysis Efficiency and Transporter Evaluation Computational Tool in Peritoneal Dialysis

Invitation to Participate:

You are invited to participate in a research study that aims to evaluate the use of artificial intelligence to predict dialysis adequacy and peritoneal membrane transporter status in peritoneal dialysis (PD) patients. Before you decide to participate it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends, relatives and your family doctor if you wish. Ask us if there is anything that is not clear and/or if you would like more information. Take time to decide whether or not you wish to take part in this research.

Purpose of the Study:

This study aims to develop and evaluate the possibility and performance of models in assessing dialysis adequacy and peritoneum transporter status in peritoneal dialysis patients.

Why have I been chosen?

You are being asked to participate because you are receiving peritoneal dialysis. We expect to recruit approximately 350 patients for this study.

Do I have to take part?

Your participation in this study is entirely voluntary. You may withdraw at any time without giving any reason. Your withdrawal will not affect your present or future medical care and the legal rights. If you feel uncomfortable in any way during the session, you may not continue to participate in the study. If you withdraw from the study, the data collected up to your withdrawal will not be used unless with your consent. You may also express your consent to research team through Informed Consent Form to allow research team to continuously use data collected before your withdrawal for research purpose. You can take time to decide whether or not you wish to take part. By signing a written consent form, you will be given a Patient Information Sheet and a signed copy of the consent form for record.

What will happen if I take part?

If you agree to participate, you will continue your routine peritoneal dialysis assessments at Tuen Mun Hospital. We will collect an extra peritoneal dialysate sample and a urine sample during your regular appointments. Under normal circumstances, no additional visits will be required for this study. Your data will be used to help develop the AI model.

Participants will be randomly assigned to either the training/validation arm or the test arm using a computer-generated randomization method at a 4:1 ratio (four participants in the training/validation arm for every one participant in the test arm).

As this study is double-blinded, the assignment for each arm cannot be disclosed to ensure unbiased results. However, participants in both arms will undergo the same procedures, and no one, including the research team and participants, will know whether they belong to the training/validation arm or the test arm. This ensures that the quality of care and the study process remain identical for all participants.

What are the alternatives for diagnosis or treatment?

Participation in this study is not mandatory for your medical care. Alternative standard diagnostic and treatment methods are available, and your doctor can continue to monitor your dialysis adequacy and transporter status without using the AI model.

Expected research period

The expected duration of your participation in this study will be approximately 12 months, during which you will continue your routine peritoneal dialysis assessments. There will be no additional visits required under normal circumstances, and the study procedures will align with your regular dialysis schedule.

Are there any risks or side effects?

This study involves no additional medical procedures beyond routine dialysis assessments. The collection of additional samples poses minimal risk.

What are the benefits of taking part?

Although there may not be direct benefits to you, the findings from this study may improve future care for PD patients by providing more accurate monitoring and better treatment options.

Significant New Information:

If new significant information becomes available during the study that may affect your decision to participate, we will inform you promptly. You may then decide whether to continue or withdraw. If you choose to withdraw, your medical care will not be affected.

Compensation for Harm:

While this study does not involve any change of your treatment or management plans, there is no designated compensation for harm resulting from participation. If you experience harm due to negligence, you may seek legal redress at your own cost. For complaints about the study, please follow the standard complaint procedure of Tuen Mun Hospital.

Cost and Payment of the Study

Apart from paying standard hospital fees for your routine dialysis care, you are not required to pay any additional fees for participating in this study. While there is no monetary reward or financial compensation for your participation, the findings from this study may benefit you and other patients in the future. By helping to develop an AI tool for dialysis adequacy and transporter status monitoring, this research could lead to more convenient care options, such as reducing the need for hospital visits to perform dialysis adequacy or transporter status assessments.

Will my participation be confidential?

Yes, all information collected about you will be kept strictly confidential and stored securely. Your identity will not be disclosed in any publication or presentation. To ensure the highest form of confidentiality, your signed consent form will be stored separately from your personal data to further protect your confidentiality. All information will be stored in the computers which are only accessible by the researchers. Data can be withdrawn and destroyed if requested by you and all data will be destroyed 7 years after the completion of the study. Access to the data will be restricted to the researchers of this study, Research Ethics Committee and the regulatory authority(ies) without violating the confidentiality of the subject, to the extent permitted by the applicable laws and regulations.

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 his/her 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.

By signing a written consent form, you are authorizing the Research Ethics Committee (REC) and the regulatory authority(ies) to get access to your study data for data verification.

Results Publication:

The results of this study may be published in academic journals or presented at medical conferences. Your identity will remain confidential, and no personally identifiable information will be included. You may request a summary of the results from the research team once the study is completed.

What happens when the research study stops?

After the study, the AI model will not be available for your ongoing care. However, your doctor will continue monitoring your condition using standard methods and advise you on appropriate treatments.

Who to contact for further information?

If you have any questions about this study, please contact:

Dr. Ka Chun LEUNG

Department of Medicine and Geriatrics, Tuen Mun Hospital

Phone: 24685111

If you have questions related to your rights as a research participant, please contact Hospital Authority Central Institutional Review Board at 2300 8472.

Version Control:

- Version: 1.0
- Date: 8th January 2025

Patient/Subject Consent Form

Title: DETECT-PD – Dialysis Efficiency and Transporter Evaluation Computational Tool in Peritoneal Dialysis

Name of Researcher: Dr Ka Chun LEUNG

Please initial box

1. I confirm that I have read and understood the information sheet dated _____/__/_____for the above study and have had the opportunity to ask question. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my present and future medical care or legal rights being affected. ☐

3. I understand that my medical notes may be read by responsible individuals concerned in this research. I give permission for these individuals to have access to my records. ☐

4. If I request to withdraw from this study, I agree / disagree my research data provided before my withdrawal will be continuously used by the investigator. ☐

5. I agree to take part in the above study and to cooperate fully with the researcher. ☐

Name of Participant (in Block Letter)	Date	Signature
Name of Impartial Witness (if applicable) (in Block Letter)	日期 Date	Signature
Name of person taking consent (if different from researcher) (in Block Letter)	Date	Signature
Researcher (in Block Letter)	Date	Signature

In case of any emergency/any questions related to this study, please contact

Dr. Ka Chun LEUNG at 24685111.

Copies to:

- Patient/Subject
- Researcher's File
- Hospital Record