HOPE-03 patient information and consent form
Pilot-scale, single-arm, observational study to assess the utility and acceptability of a machine learning algorithm assessing fluid status in haemodialysis patients

Haemodialysis Outcomes & Patient Empowerment study 03 (HOPE-03)

Principal Investigator: Prof. Conall O'Seaghdha, Beaumont Hospital, Dublin 9. (Consultant Nephrologist & Renal Transplant Physician)

Principal Investigator contact number: 01 809 2730.

Co-investigator name: Dr Vicki Sandys, Beaumont Hospital, Dublin 9. (Research Registrar)

Co-investigator contact number: 01 809 2730.

Research nurse name: Anna Ninan, Royal College of Surgeons in Ireland, Dublin 9.

Research nurse contact number: 01 809 2730

Data Controller: Royal College of Surgeons in Ireland, Dublin 9.

Data Processor: patientMpower Ltd., 60 Merrion Square South, Dublin D02 KX26.

Data Protection Officer's identity: Donall King; Data Protection Officer, Royal College of Surgeons in Ireland, Dublin

Data Protection Officer's contact: dataprotection@rcsi.ie

Introduction

You are invited to take part in a research study at Beaumont Hospital. Before you decide whether or not you wish to take part, please read this information carefully and feel free to discuss it with family, friends and your GP if you wish. Take time to ask questions. You should clearly understand the study before deciding whether or not to take part.

You don't have to take part in this study. If you decide not to take part it won't affect your future medical care.

You can change your mind about taking part in the study any time you like. Even if the study has started, you can still opt out. You don't have to give us a reason. If you do opt out, rest assured it won't affect the quality of treatment you get in the future.

What is the purpose of this study?

We are assessing a computer program that has been developed to predict fluid status in patients who need dialysis. This study is being carried out to see if this computer program can calculate your fluid status as accurately as usual methods used in the clinic. At present, it is difficult for doctors and nurses to accurately assess your fluid status, and whether your 'dry weight' is best for you.

This computer program combines information collected during a routine haemodialysis treatment, such as your blood pressure and fluid removal, and estimates your fluid status. It has been studied and tested against gold standard measures in a computer setting, using the information from >10,000 dialysis patients.

Why am I being asked to take part?

We are interested in seeing if the computer program works in dialysis patients in a usual care setting.

People who need dialysis regularly need fluid taken off by dialysis to prevent complications from over-hydration. It is important for patients on dialysis to know their target weight so that the right amount of fluid can be taken off on dialysis. If too much fluid is taken off on dialysis, people can experience symptoms such as muscle cramps, chest pain, or dizziness. If too little fluid is taken off people may experience symptoms such as difficulty breathing or leg swelling. Over time, having too much or too little fluid in the body can damage organs such as the heart.

It is difficult at present to accurately estimate your fluid status. Your target weight may change over time, such as when you lose or gain physical weight. In these circumstances, your target weight after dialysis may change. This may go unnoticed, and patients may either have too much or too little fluid taken off on dialysis.

A computer program that could calculate patients' fluid status every few weeks and provide patients, nurses and doctors with updates would be useful.

The study will only enrol people who regularly need dialysis.

What will happen if I volunteer? How long is the study?

We hope to enrol about 20 people in this study. The study will last for about eight weeks. During the study, you will visit the centre for dialysis on the usual days. No extra visits are needed. There will be no change to your usual dialysis visit schedule or treatment and you will not be asked to make any changes to your medicines or diet.

Throughout the study you will have dialysis as usual and all usual measurements will be recorded (for example, weight, blood pressure, monthly bloods, volume of fluid removed and symptoms before, during and after dialysis).

You will **not** be asked to make changes to your dry weight based on the computer program output.

At the first study visit and at the visits at Week 2, Week 4, Week 6 and Week 8, when you attend for dialysis an additional measurement of your fluid levels will be carried out shortly before dialysis. This measurement is called bioimpedance. It involves two electrodes being attached to your hand and foot, and uses a painless very low level electric current to estimate fluid levels. No injections are needed and the procedure is painless. Bioimpedance takes about 5- 10 minutes in total, so at these five visits you will be in the dialysis centre for about 10 minutes longer than usual. At these visits, you will also be asked questions about any symptoms in the past 2 weeks.

After about eight weeks the study will be concluded.

Are there any benefits from taking part?

You will not benefit directly from taking part in this study. It will not have an impact on your usual medical care. By taking part, you will help the research team better understand how useful the computer programme is for dialysis patients in a usual care setting. If the computer programme is successful, it could be used to help patients manage their fluid levels in the future.

Are there any risks in taking part?

It is not expected that there are any additional risks from participation in this study. Throughout the study you will continue to attend the dialysis clinic to your usual

schedule and your health will be monitored as usual. During the study, five visits to the dialysis clinic will be about 10 minutes longer than usual to allow for the bioimpedance tests.

Confidentiality and data protection

1. We will be accessing your electronic medical records in order to collect data for this study. The consultant nephrologist responsible for your care will be informed of your participation in the study.

2. This study is being conducted as part of scientific research in the effective delivery of dialysis treatment and your collected data would contribute to this. The legal basis for processing patient data is written consent from the patient. The patient consent form asks patients to give explicit consent to having their data processed as part of participation in the study. You should only take part in the study if you are comfortable with this approach. If you do not wish your data to be used you should not give your consent to take part in the study.

3. All of the information collected about you for this study is considered to be confidential and will be managed accordingly. Only the clinical, nursing and research team at the study centre will know the identity of the patients who take part in this study. The identities of patients will not be published or disclosed to anyone else. This study is part of a long-term research project doing research on dialysis. This study is a collaboration between Beaumont Hospital and patientMpower Ltd., Dublin. The information will not be shared with any third parties. It will be pseudonymised. That means that the information will be linked to a unique identification number and not your name. The information will be encrypted and stored securely by patientMpower Ltd (on behalf of the partners in the study). We will be using your pseudonymised personal data collected in this study in our research so that we can better understand if the computer programme works when it is compared with the usual methods of fluid assessment. This may help guide future research projects in dialysis.

4. Because data obtained during this study could help future research in dialysis we would like to retain this information for five years. For example, this data could help us design and run other studies in future if given permission by the appropriate research ethics committees (e.g. at Beaumont Hospital).

   Your data from this trial may be used within the confines of future research conducted by this study group. This research group is conducting a series of trials over 3-5 years. The ultimate goal of this research is to help dialysis patients manage their fluid status using a combination of wearable health technology, mobile health apps, and computer programs. Your data may be used to improve the accuracy of the computer program in predicting dry weight, to help design future studies, or to guide the creation of a mobile health app. You have an option to
   i) consent for your data to be used in this trial only
   ii) consent for your data to be used in this trial and future research.

You have the option to withdraw or change your consent at any point.

5. patientMpower Ltd. stores the data in secure cloud storage and has strict security measures in place to help protect against loss, misuse and alteration of any data under their control. However, with any data processing there are risks and we can not guarantee that the database will be 100% secure. If there is a personal data breach, patientMpower Ltd. will report it to the Data Protection Commissioner.

6. Taking part is entirely voluntary and you can change your mind at any time during the study. You can stop taking part in the study or choose not to consent to your personal information being analysed. This will not affect your future treatment in any way.

   If you wish to withdraw your consent, please contact the research nurse or research register in this trial. You can use the number provided in this information leaflet, or ask your dialysis nurse to contact the research nurse/register at your next dialysis visit.

7. If you have any concerns about data protection issues you have the right to lodge a complaint with the Data Protection Commissioner.

8. (8, 10, 12) You can request a copy of your data collected in this study or request deletion or correction of your data collected in this study at any time. You can request to restrict access to your data at any time, and can request for your data to be moved from one data controller to another. Please contact the research team if you would like to do this.

9. You have a right to restrict or object to processing of your data unless this would it impossible or difficult to conduct research. For example, you opt to have your data collected and stored, but not shared.

11. You have a right to have your personal data deleted, unless this request would make it impossible or very difficult to conduct the research. e.g. they wanted to delete their data at the end of a research project just before it is due to be published.

13. Some of your personal data may be used in automated decision making. This is where personal data, such as age and gender, is used to predict aspects of your health or behaviour. In this study, pseudonymised personal data may be used by the computer algorithm to predict your dry weight.

14. You have a right to object to the use of your personal information if you wish.

15. The results of the study will help the research partners to understand how an algorithm could be used to help manage fluid levels in people who need dialysis. The study is part of a long-term research project (HOPE) to try to improve delivery of

dialysis care. We would like your permission to use data collected in this study as part of this future research. (These data would be pseudonymised.) For example, the data in this study could be used to help us decide how many patients might be needed for future studies.

Will it cost me anything to take part?

No extra visits to the dialysis clinic are needed and there will be no costs to you to take part. You will not receive any financial compensation to take part in this study.

Who is organising and funding the research?

The study is being conducted as part of the Haemodialysis Outcomes & Patient Empowerment (HOPE) project supported by the Disruptive Technology Innovation Fund of Ireland (DTIF). HOPE is a collaboration between the Royal College of Surgeons in Ireland, Beaumont Hospital, patientMpower Ltd., Dublin and Sixty (registered as Design to Value Ltd.), Inishannon, Co. Cork. The study is funded by the DTIF grant through Enterprise Ireland.

Has the study been reviewed by an ethics committee?

The study has been reviewed and approved by the Beaumont Hospital Ethics (Medical Research) Committee.

How will the study results be used?

The results of the study will help the research partners to understand how an algorithm could be used to help manage fluid levels in people who need dialysis. The study is part of a long-term research project (HOPE) to try to improve delivery of dialysis care. A summary of the results will be communicated to all patients who take part. The results of the study will also add to the medical literature that already exists about kidney disease and dialysis. We hope to be able to present our findings at medical conferences and as articles in medical journals. Any publications will be based on a summary of the information from all participants and will be anonymous.

The dialysis centres and patients will be provided with a summary of the study results.

Contact details
If you have any further questions on this study please contact:

Name: Anna Ninan

Phone: 01 809 2730

Haemodialysis Outcomes & Patient Empowerment study 03 (HOPE-03)

PATIENT CONSENT FORM

Study title: Health Outcomes and Patient Empowerment Study 03 (HOPE-03)

I have read and understood the **Information Leaflet** about this research project. The information has been fully explained to me and I have been able to ask questions, all of which have been answered to my satisfaction.	**Yes •**	**No •**
I understand that I don't have to take part in this study and that I can opt out at any time. I understand that I don't have to give a reason for opting out and I understand that opting out won't affect my future medical care.	**Yes •**	**No •**
I am aware of the potential risks, benefits and alternatives of this research study.	**Yes •**	**No •**
I give permission for researchers to look at my medical records to get information. I have been assured that information about me will be kept private and confidential.	**Yes •**	**No •**
I have been given a copy of the Information Leaflet and this completed consent form for my records.	**Yes •**	**No •**
I consent to take part in this research study having been fully informed of the risks, benefits and alternatives.	**Yes •**	**No •**
I give informed **explicit** consent to have my data processed as part of this research study.	**Yes •**	**No •**
I consent to be contacted by researchers as part of this research study.	**Yes •**	**No •**

FUTURE CONTACT [please choose one or more as you see fit]		
OPTION 1: I consent to be re-contacted by researchers about possible future research **related** to the current study for which I may be eligible.	**Yes •**	**No •**
OPTION 2: I consent to be re-contacted by researchers about possible future research **unrelated** to the current study for which I may be eligible.	**Yes •**	**No •**

STORAGE AND FUTURE USE OF INFORMATION		
RETENTION OF RESEARCH MATERIAL IN THE FUTURE [please choose one or more as you see fit]		
OPTION 1: I give permission for material/data to be stored for *possible future research* ***related*** to the current study ***only if consent is obtained*** at the time of the future research but only if the research is approved by a Research Ethics Committee.	Yes •	No •
OPTION 2: I give permission for material/data to be stored for *possible future research* ***related*** to the current study ***without further consent being required*** but only if the research is approved by a Research Ethics Committee.	Yes •	No •
OPTION 3: I give permission for material/data to be stored for *possible future research* ***unrelated*** to the current study ***only if consent is obtained*** at the time of the future research but only if the research is approved by a Research Ethics Committee.	Yes •	No •
OPTION 4: I give permission for material/data to be stored for *possible future research* ***unrelated*** to the current study ***without further consent*** being required but only if the research is approved by a Research Ethics Committee.	Yes •	No •
OPTION 5: I agree that some future research projects may be carried out by researchers working for commercial/pharmaceutical companies.	Yes •	No •
OPTION 6: I understand **I will not be entitled to a share of any profits** that may arise from the future use of my material/data or products derived from it.	Yes •	No •

Patient Name (Block Capitals)	Patient Signature	Date
---	---	---
Translator Name (Block Capitals)	Translator Signature	Date
---	---	---
Legal Representative/Guardian Name	Legal Representative/Guardian Signature	Date

To be completed by the Principal Investigator or nominee.

I, the undersigned, have taken the time to fully explain to the above patient the nature and purpose of this study in a way that they could understand. I have explained the risks involved as well as the possible benefits. I have invited them to ask questions on any aspect of the study that concerned them.

Name (Block Capitals)	Qualifications	Signature	Date

3 copies to be made: 1 for patient, 1 for PI and 1 for hospital records.