

PARTICIPANT INFORMATION SHEET & INFORMED CONSENT FORM

PHOSPHATE

Pragmatic randomised study of High Or Standard PHosphAte Targets in End-stage kidney disease - **The PHOSPHATE Study**

You are being invited to take part in a research study. Before deciding whether to take part, you need to understand why this research is being done and what it involves. Please take time to 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.

INTRODUCTION

Based on current evidence, it is unclear if lowering blood phosphate towards a normal level is always a good option for patients receiving dialysis. This research study is trying to find out if controlling blood phosphate levels results in a longer life and a better quality of life. Phosphate levels can be affected by your diet, dialysis and medications called phosphate binders. This study will test whether a lower or higher phosphate level improves the health of patients on dialysis treatment. It is a randomised study. This means that if you take part in the study, you will be “assigned” to either a higher or lower blood phosphate target by chance, like tossing a coin. It is up to your own doctor to recommend changes to your diet, adjust your dialysis prescription or prescribe phosphate binders to meet this target. The study will include 3,600 patients from Australia, New Zealand, Canada and the UK. We expect about 2000 to be enrolled from up to 60 centres across the UK.

Kidney patients helped to design this study, and a patient is part of the study team.

This study is designed in a new way that is aimed at limiting the burden of taking part in research on both patients and staff. If you take part, the additional burden on your time is limited to the following:

1. One assessment by your study doctor or nurse at the start of the study, either during your usual dialysis treatment or at your usual clinic visit
2. A short questionnaire once every 6 months as long as the study continues. You can choose how to do this – by letter or by telephone, either from home or at your dialysis unit.

THE STUDY DOES NOT REQUIRE ANY EXTRA HOSPITAL VISITS OR PROCEDURES.

SECTION 1: Purpose of the study, and what will happen to me if I take part

SECTION 2: Detailed information about the study

Section 1: Purpose of the study and what will happen

1. What is the purpose of the study?

Dialysis patients often have higher levels of phosphate compared with people with healthy kidneys. Research suggests that higher phosphate levels may increase the risk of heart disease and death. The current treatment guidelines suggest that high phosphate levels should be reduced towards the normal level and standard care is to reduce these levels to less than 1.5 mmol/L. But evidence for these guidelines needs to be improved. Doctors don't know if lowering blood phosphate towards a normal level is always a good option for patients receiving dialysis.

Phosphate levels can be reduced by diet, dialysis and medication. Medications used to reduce phosphate are called phosphate binders. Phosphate binder use increases the number of pills taken by dialysis patients. These medications can also cause side effects.

The study will examine whether reducing phosphate levels in dialysis patients will improve:

- Life expectancy
- Heart health
- How patients feel or function.

2 What is the treatment being tested?

This study will compare two different target blood phosphate levels.

1. **Lower Phosphate group** – aims to keep blood phosphate levels under 1.50 mmol/L which is the current standard care. If you are assigned to this group, your doctor may change the management of your phosphate levels. This will depend on your current phosphate level and local practice in your hospital. Changes may include advice on restricting foods with high phosphate content and an increase in the number of phosphate-binder pills you need to take.
2. **Higher Phosphate group** – aims to keep blood phosphate levels between 2.00 and 2.50 mmol/L. If you are assigned to this group, your doctor will ask you to stop all phosphate-binder pills. Your doctor will advise you to take phosphate-binder pills only if your phosphate level is above 2.50 mmol/L.

3 Why have I been invited?

You are invited to participate in this study because

- you have regular dialysis; and
- you take medication to control your phosphate levels.

4 Do I have to take part?

Participating in this study is completely voluntary. If you decide to participate you will be asked to sign an Informed Consent Form, however you are still free to change your mind and stop the treatment only, or leave the study completely at any time without giving a reason. Further details about withdrawing from the study is provided in point 14. If you chose not to participate or to leave the study, your future medical treatment and normal standard of care will not be affected in any way.

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

Consent

You will be given enough time to decide whether you would like to take part in the study. You will have the opportunity to ask any questions you may have about the study and to discuss these with your doctor. This may be by telephone or video call. 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 provided with a copy of this to take away and refer to later. Even if you sign this consent form, you can still withdraw your consent at any time without having to give an explanation. After consenting to participate in the study, you will be given a unique study number. This number will be used instead of your name on study documentation to help protect your confidentiality.

The longest time you will be in the study is 7 years, but on average it will be 4.5 years.

Randomisation

This study is a **randomised** study. What does that mean?

As we sometimes don't know which way of treating patients is best, we need to compare different treatments. We put people into groups and give each group a different treatment. You will be allocated one of the treatments for this study in a random way (by chance), so we can be sure that the two groups are as similar as possible. This way, any differences between groups can be attributed to the treatment they received rather than any other differences between groups. In this study, the size of the groups will be the same, therefore you will have a 50% chance of being in either of the following two treatment groups:

1. **Lower Phosphate group** – If you are assigned to this group, your doctor may change the management of your phosphate levels to keep your blood phosphate levels under 1.50 mmol/L. This is the current standard care for managing phosphate levels.
2. **Higher Phosphate group** – If you are assigned to this group your doctor will advise you to take phosphate-binder pills only if your phosphate level is above 2.50 mmol/L. You will also be able to relax your dietary phosphate restriction if levels remain below 2.50 mmol/L.

You will be told which treatment group you have been assigned to.

Baseline Visit

Once you have given consent and been assigned to your treatment group, the study doctor or nurse will record your demographic information including date of birth, age and race. Your study doctor will record your most recent phosphate levels. Your study doctor will also discuss the recommended methods to reach the target phosphate level of the treatment group you have been assigned to. For most patients, this will be on the day of agreeing to participate.

You will be asked to complete a short questionnaire about your quality of life. You will be asked questions about the following topics: Mobility, Self-Care, Usual Activities, Pain and Discomfort, Anxiety and Depression and overall how good or bad you feel your health is. This is so we can get an idea if you feel health is currently impacting on your quality of life.

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**6-Monthly
Questionnaire**

As a part of the PHOSPHATE study, you will be asked to complete a short questionnaire about your quality of life at the beginning of the study and then every 6 months (for up to 7 years). Each time, it will take approximately 5 minutes to complete. One of these questionnaires will be provided to you by your research team at your dialysis unit, at 12 months.

For the other questionnaires, you will be given the option of conducting these assessments in one of 2 ways:

1. Post (via return of a self-addressed, stamped envelope)
2. Telephone

The study team will send you the questionnaire by mail or will telephone you when the questionnaire becomes due.

Content of the questionnaire:

You will be asked about:

- Repeating the short **health questionnaire** you completed at the start of the study

You will also be asked to confirm your preferred method of contact for the future questionnaires and to confirm our records of your contact details are up to date. This study may last for up to 7 years or more.

**Data
Collection**

For all participants, we will carry out study assessments via the collection of routinely held data. For this, we will use information already collected about you by other organisations as described below. This will take the place of many of the hospital visits that would normally form part of a study like this one. In order to identify and obtain information about you, we will be required to send personal identifiers (forename, surname, sex, date of birth, postcode, and NHS/CHI number) to these organisations. The information they return to us may also contain some of these personal identifiers.

All data collected in this way will be stored on highly secure encrypted servers held within the University of Cambridge and will be accessible only to the small team of researchers directly involved with the study. We will need to retain this data for the duration of the study and then archive it for up to 15 years in accordance with the relevant clinical study regulations and legislation in force at the present time. The data will then be destroyed.

Data will be collected from a number of sources:

- a) **The UK Renal Registry (UKRR)** - The UKRR is part of the UK Kidney Association and collects data from renal centres and hospital laboratories across the UK. This is so that they can publish annual reports on national averages and long-term trends. By collecting information from the UKRR, it means that we can use the data they already hold rather than having to ask participants to attend hospital for extra study visits.

The data collected by the UKRR includes clinical test results (such as blood and urine tests). The test results are sent to the UKRR from hospitals daily, and with your consent to participate in PHOSPHATE, the UKRR can share them with the study team as soon as they are available. Being able to notify your local research team quickly if your phosphate level needs adjusting is very important for this study.

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If you are interested in being able to see your test results you can sign up to a service called Patients Know Best. Your local study team can help you to do this if you wish. You do not have to sign up to Patients Know Best to take part in this study.

b) **NHS ENGLAND** - NHS England is a national provider of information on healthcare in the United Kingdom and links this information to the datasets below.

1. **Hospital Episode Statistics (HES)** - The NHS in England collects information on all hospital admissions, including when, why and for how long they happen. By collecting information from HES, it means that we can use the information the NHS already holds rather than having to ask patients to attend hospital for extra study visits. This information will be used in the study to help provide some of the results for this trial.
2. **Civil Registrations of Death**- In the unfortunate event that a person dies, this information is obtained from civil registration mortality data by the NHS England. Because it is important for us to know what happens to patients in the study, NHS England will provide the study team with any information they might have on participants in the study.

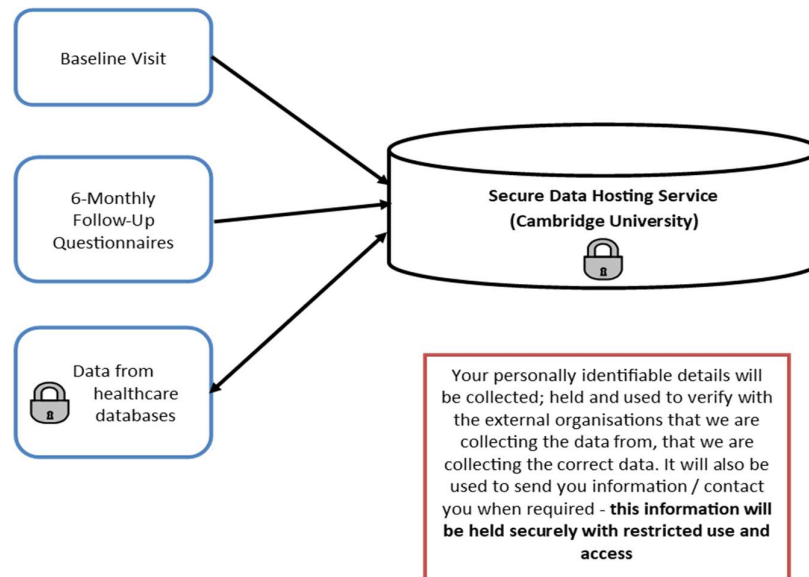
Equivalent national health record organisations exist in Wales (Secure Anonymised Information Linkage, Public Health Wales) and Scotland (electronic Data Research and Innovation Service, Public Health Scotland). If you live in these areas, the study team will obtain similar central healthcare records from these sources.

If your dialysis unit does not contribute data to the UKRR then your test result data will be collected from your hospital's electronic medical record system (if possible) or submitted by your local research team at your dialysis unit.

By consenting to the PHOSPHATE study, you agree that the study team will provide your personal data to the organisations listed above (or equivalent organisations in the devolved nations) for linkage to the specified datasets. These datasets from separate organisations may be linked as part of the analysis for the trial.

This study may last for up to 7 years and information will be collected from the organisations above until the end of the study. We will contact you, by your preferred method of communication, to confirm once the trial has ended.

The picture below shows how the information we collect will be kept secure:



6. What will I have to do?

You and your doctors will know which treatment group you are in. Your study doctor will tell you how your blood phosphate levels will be managed. If you agree to be in the study, apart from blood phosphate target level, there will be no changes to your usual care. This includes medical, kidney disease and dialysis-related care.

You will not be able to take part in this study if you are pregnant or breastfeeding. You should not participate in this study if you are planning to become pregnant during the study. If you do become pregnant, you will be withdrawn from the study so that you can receive the adjusted dialysis treatment required in pregnancy.

You should tell the study team if you feel unwell or different in any way. 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.

7. What are the side effects of the interventions being tested?

The treatments to be tested in this study are 2 different blood phosphate levels: Lower and Higher Blood Phosphate groups.

Risks associated with a **lower** blood phosphate may include:

- Taking more phosphate-binder medications. Large numbers of phosphate-binder pills can cause reduced appetite and quality of life.
- Side effects caused by the individual type of phosphate binder that is prescribed by your doctor. It is important to remember that most side effects will settle when you stop taking these medications. Tell your study doctor immediately about any new or unusual symptoms that you get.

Risks associated with a higher blood phosphate may include:

- Increased risk of hardening of blood vessels and heart valves, and thickening of heart muscle.
- Potentially a higher rate of cardiovascular events, such as heart attack and stroke.
- Increased levels of parathyroid hormone (PTH). High levels may cause bone pain. Dialysis units routinely measure PTH. You may need extra medication or dietary advice to control high levels.

It is not possible to quantify exact risk since although increased phosphate levels have been associated with these events, many other factors, such as co-existing diabetes, age, length of time of dialysis and other medical conditions also play important roles, and it is impossible to separate out the contributions of each factor.

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

Medical treatments often cause side effects. You may have none, some or all of the effects listed above, and they may be mild, moderate or severe. If you have any of these side effects, or are worried about them, talk with your study doctor. Your study doctor will also be looking out for side effects and any other medical events that might be associated with participation in the trial.

9. What are the possible benefits of taking part?

Taking part in this study may or may not make your health better compared to receiving your routine medical care. The information from this study may help doctors learn more about treating high phosphate levels. However information collected as part of your participation in this study may benefit patients with kidney disease in the future.

10. What are the alternatives for treatment?

You do not have to take part in this research project to receive treatment at this hospital.

11. What happens when the study stops?

You may be able to continue with the phosphate-binder medication, in addition to dietary and dialysis adjustments, at the end of this study. Your treating doctor will decide the dose. Once the study is complete and the results are known, a written plain English summary of the results of the study will be made available to your study staff. You can request a copy of this summary from the study staff.

12. Will I be paid for taking part?

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. However, the study has specifically been designed so that no hospital visits or procedures are required in addition to your standard care.

Section 2: Trial 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 will 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 that 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 stop participating in this study at any time. You can do this by speaking to your study doctor. You do not need to provide a reason, and your decision will not affect your future care or medical treatment. If you decide to stop participating your phosphate level will continue to be managed as per local standard of care.

You can decide,

1. To withdraw from study treatment but allow us to continue questionnaire completion AND to continue to data linkage.
2. To withdraw from study treatment AND stop questionnaire completion BUT allow us to continue to data linkage.
3. To withdraw completely from the study – study treatment, questionnaire completion and data linkage ceases.

If you choose to withdraw completely from the study, your data will be collected up to the date that you chose to stop participating in the trial. Due to the availability of routinely held data, this data may be received after the date that you chose to stop participating. The data collected up to the date that you chose to stop participating in the trial will continue to be used in the analysis.

The study doctor may 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 study withdrawal could include:

1. You have experienced a serious side effect
2. You are unable to complete the visits, medication or study documentation as required
3. You become pregnant or plan to become pregnant
4. The study doctor feels you no longer appear to benefit from the treatment.
5. You have had a kidney transplant.

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.

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In the event that something does go wrong and you are harmed by taking part in the research and this 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 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

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 do this through the NHS complaints procedure. In the first instance it may be helpful to contact the *(to be completed locally as appropriate – in England this will refer to the Patient Advice and Liaison Service (PALS))* at your hospital.

16. Will my taking part in this study be kept confidential?

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. The Sponsor organisations will keep identifiable information about you for 30 years after the study has finished to ensure your safety and allow the study to be reviewed by the authorities after it is finished.

Your rights to access, change or move your information are limited, as the Sponsor organisation(s) need to manage your information in specific ways in order for the research to be reliable and accurate. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how the Sponsors use your information using the information below:

- For Cambridge University Hospitals NHS Foundation Trust, please visit:
<https://www.cuh.nhs.uk/patient-privacy/> or email The Data Protection Officer at:
cuh.gdpr@nhs.net

- For University of Cambridge, please visit:
<https://www.medschl.cam.ac.uk/research/privacy-notice-how-we-use-your-research-data/> or email

The Information Governance team at: researchgovernance@medschl.cam.ac.uk

For participants recruited at CUH (where the Sponsor is also the site):

Cambridge University Hospitals will collect your name, NHS number and contact details to contact you about this study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from the Sponsors and regulatory organisations may look at your medical and research records to check the accuracy of this study. Cambridge University Hospitals will pass these details to the Sponsors along with the information collected from *you and your medical records*. The only people in the Sponsor organisations who will have access to

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information that identifies you will be people who need to contact you in relation to this study and to audit the data collection process. Cambridge University Hospitals will keep identifiable information about you from this study for 5 years after the study has finished.

For participants recruited at other participating sites:

(Add site name) will pass personal information about you (full name, sex, date of birth, home address, postcode, telephone number, and NHS/CHI number) to the Sponsor organisations to collect information about you from the healthcare organisations explained in point 5 and send you the follow-up questionnaire questionnaires. **Specify where patient identifiable information will be stored, who will have access to personal data and what measures are in place to ensure patient confidentiality in line with information provided in the IRAS form.**

(Add site name) will keep identifiable information about you from this study for **##** years after the study has finished.

All information collected about you as a result of your participation in the study will be kept strictly confidential. Your personal and medical information will be kept in a secured file and be treated in the strictest confidence.

Once you have agreed to participate in this study you will be allocated a Trial ID Number. This is a unique study number which will be used on all your study documentation along with your date of birth. Your date of birth is considered to be personal information. We collect this personal information on study documentation to help ensure that the data we receive as part of your study participation is correctly allocated to you. By cross checking these two unique references we can ensure the integrity of the data.

The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details. Only anonymous study data, without any personal information will be published at the end of the study.

When you agree to take part in this study, the information about your health and care may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research.

This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research, and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance.

We will need to inform your GP of your participation in this study so that any medical decisions made by your GP account for any treatment you are receiving as part of this study.

17. What will happen to my samples?

No blood samples will be collected as part of this study. The measurement of blood phosphate levels is part of routine clinical care in dialysis patients.

18. What will happen to the results of the study?

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 results of this study are available they may be

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published in peer reviewed medical journals and used for medical presentations and conferences.

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

At the end of the study, we will contact you, via your preferred contact method, to inform you of the study findings.

19. Who is funding the study?

The study is being funded by the National Institute of Health Research in the UK.

20. 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 and given favourable opinion by East of England - Cambridge Central Research Ethics Committee.

21. Further information and contact details

For further information about the study, please contact *[Sites to enter name, address, email address, telephone numbers including the 24 hour emergency contact number]*.

The Patient Advice and Liaison Service (PALS) should be contacted for any complaints. Your local PALS is *[Enter local details]*

Independent advice may be sought from the British Kidney Patient Association,

3 The Windmills, St Mary's Close, Turk Street, Alton GU34 1EF

Telephone: 01420 541424 Fax: 01420 89438

Email: info@britishkidney-pa.co.uk Website: <http://www.britishkidney-pa.co.uk/>

In the event of an emergency please contact:

List local 24 hour emergency contact detail here – this must match the information provided on the patient ID card and will be used to test the out of hours procedure for the study.

INFORMED CONSENT FORM

Trial Title: Pragmatic randomised study of High Or Standard PHosphAte Targets in End-stage kidney disease - **The PHOSPHATE Study**

Principal Investigator: _____

Participant Number: _____

If you agree with each sentence below, please initial the box

INITIALS

		INITIALS
1	I have read and understood the Participant Information Sheet version 3.2, dated 05 Dec 2023 for the above 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.	
3.	I understand that sections of my medical notes or information related directly to my participation in this study may be looked at by responsible individuals from the sponsor, regulatory authorities and research personnel 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.	
4.	I understand that my GP will be informed of my participation in this study and sent details of the PHOSPHATE study.	
5.	I understand that personal information about me will be collected and used in accordance with the information sheet version 3.2, dated 05 Dec 2023. This information will be kept in the strictest confidence and none of my personal data will be published.	
6.	I understand that the study team will send my name, sex, date of birth, postcode, and NHS/CHI number to the national health record organisations described in point 5 to provide information about my health status as part of this study. I understand that, if I live in Scotland or Wales, this information will be obtained from the equivalent sources described.	
7.	I understand that the UKRR will receive a data feed from my hospital and will share my test results with the PHOSPHATE study team. My results will not be sent to Patients Know Best unless I choose to sign-up.	
8.	I understand that, at the end of the study, my anonymised study information might be shared with other researchers outside the University of Cambridge, both in the United Kingdom and abroad.	
9.	I have read and understood the compensation arrangements for this study as specified in the Participant Information Sheet.	
10.	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.	
11.	I have read and understood my responsibilities for the study as listed in section 5.	

I agree to participate in this study:

Name of patient:

Signature

Date:

Time of Consent (24hr clock) _____:

Name of person taking consent:

Signature:

Date:

Time of Consent (24hr clock) _____:

1 copy for the patient, 1 copy for the study team, 1 copy to be retained in the hospital notes.

PHOSPHATE

Pragmatic randomised study of **High Or Standard PHosphAte T**argets in **E**nd-stage kidney disease - **The PHOSPHATE Study**

PHOSPHATE Trial Summary

- ✚ The PHOSPHATE trial aims to find out if controlling blood phosphate levels results in a longer life and a better quality of life for dialysis patients.
- ✚ Dialysis patients often have higher levels of phosphate compared with people with healthy kidneys. Research suggests that higher phosphate levels may increase the risk of heart disease and death. The current treatment guidelines suggest that high phosphate levels should be reduced towards the normal level. But evidence for these guidelines needs to be improved. Doctors don't know if lowering blood phosphate towards a normal level is always a good option for patients receiving dialysis.
- ✚ The PHOSPHATE study will compare two different target blood phosphate levels:
 - 1) **Lower Phosphate group** – aims to keep blood phosphate levels under 1.50 mmol/L. If you are assigned to this group, your doctor may change the management of your phosphate levels. This will depend on your current phosphate level and local practice in your hospital. Changes may include advice on restricting foods with high phosphate content and an increase in the number of phosphate-binder pills you need to take.
 - 2) **Higher Phosphate group** – aims to keep blood phosphate levels between 2.00 and 2.50 mmol/L. If you are assigned to this group, your doctor will ask you to stop all phosphate-binder pills. Your doctor will advise you to take phosphate-binder pills only if your phosphate level is above 2.50 mmol/L.
- ✚ The PHOSPHATE trial **does not require any extra hospital visits** or procedures.
- ✚ We will ask you to complete **a short questionnaire** once every 6 months as long as the study continues. You can choose how to do this – by letter or by telephone, either from home or at your dialysis unit.
- ✚ For all patients, we will carry out study assessments via the collection of information already collected about you by other organisations, such as: the United Kingdom Renal Registry (UKRR) and NHS England (Public Health England) and its equivalent in Scotland and Wales.
- ✚ The results of this trial will help kidney doctors and nurses to understand whether lowering blood phosphate towards a normal level is always a good option for patients receiving dialysis.
- ✚ With your help, we can answer this very important question.

If you have any questions about the trial, please do not hesitate to ask your research team.

THANK YOU FOR YOUR HELP