TO BE PRINTED ON HEADED PAPER

PARTICIPANT INFORMATION SHEET & INFORMED CONSENT FORM

Survival **Imp**rovement with Colecalciferol in Pat**ie**nts on **D**ialysis

You are being invited to take part in a research study.

Before deciding whether to take part, you need to understand:

1. Why this research is being done and
2. What it involves.

Please take time to read the following information carefully and discuss it with friends, relatives or your personal doctor (i.e. general practitioner or primary care physician) if you wish. Please ask us if there is anything that is not clear, or if you would like more information. Please take time to decide whether or not you wish to take part.

INTRODUCTION

This study will test whether "natural" vitamin D (called colecalciferol, and made by the body when sunlight falls on the skin) 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 one of two treatment groups by chance, like tossing a coin. One group will be given a dose of colecalciferol (most likely in the form of 3 small capsules) once every two weeks. The other group will continue their usual treatment. The study will include 4,200 patients from up to 65 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. One extra blood test (to measure vitamin D), added to your usual blood tests

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 IF YOU TAKE PART

1. What is the purpose of the study?

This study will test whether patients on dialysis stay healthier for longer if they take the "natural" form of vitamin D, called colecalciferol. This is currently rarely used. Instead, most patients receive "artificial", active forms of vitamin D such as alfacalcidol and paricalcitol.

People need vitamin D to stay healthy. Getting calcium from the diet into bones depends on vitamin D. Low vitamin D levels (vitamin D deficiency) leads to soft bones, fractures, weak muscles, heart and blood pressure problems, and may increase the risks of infections and cancer. People with kidney failure on dialysis often have low vitamin D levels for at least 3 reasons.

1. When kidneys fail, the body is less efficient at making its own vitamin D.
2. Foods rich in vitamin D are mostly restricted because of high phosphate or potassium.
3. Patients are usually asked to avoid excessive sunlight or wear sunscreen to avoid skin problems such as cancer.

Natural vitamin D is not usually given to dialysis patients, because doctors used to believe that the body could not use natural vitamin D unless the kidneys were healthy (and for this reason, the packaging of these vitamin D products often advise that they should be not be taken by patients with kidney problems). It turns out that this is not the case: the body does use natural vitamin D even in people who have no kidneys. This is why we now need to test if natural vitamin D is better or worse than the artificial and active forms of vitamin D treatments we currently use.

2. What is the medicine being tested?

The medicine used in this study is the natural form of vitamin D, called colecalciferol. It is identical to the vitamin D made by your own skin in sunlight. This form of vitamin D is added to many foods as a supplement, and is available over the counter (OTC) and as a licensed medicine in the United Kingdom.

It usually comes as a small capsule, about the size of a pea. If you are "assigned" to the vitamin D group, you will need to take 3 of these capsules (60,000 international units) once every two weeks.

It is also available as a suspension (liquid), or as a tablet rather than a capsule. The exact form that you are given may vary and will depend on local availability or preference. Different forms contain different inactive 'filler' ingredients, for example, some capsule formulations contain gelatin. You should tell your study doctor if there are any ingredients you are unable or unwilling to take, for example, due to hypersensitivity or religious beliefs. Your study team will then check that a suitable product is available

3. Why have I been invited to participate in this study?

You have been invited to participate because you have kidney failure that requires dialysis. The study treatment, colecalciferol, may improve health, quality of life and life expectancy in people with your condition.

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 leave the study at any time without giving a reason. If you chose not to

participate, or if you 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?

Screening

If your doctor thinks that the study will be suitable for you, and that you will be eligible for the study, you will be given detailed information to read through.

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. If you agree to participate, you will be asked to sign the consent form at the end of this information sheet. It may also be possible to discuss the trial and each point on the consent form with your doctor remotely and be able to sign the consent form during that conversation.Even if you sign this consent form, you can still withdraw your consent at any time without having to give an explanation. If relevant to you, you will be asked to have a pregnancy test.

Treatment allocation

You will be allocated to one of the treatment groups for this study in a random way (by chance), much like flipping a coin. You will have a 50% chance of being in either of the following two treatment groups:

1. **Colecalciferol group:** If you are assigned to this group you will receive all your usual treatments as recommended by your doctor (*standard care*). In addition, you will be prescribed the study drug, colecalciferol (60,000 IU once every two weeks). You should not take any extra colecalciferol from outside of the trial if you are assigned to this group.
2. **Standard Care group:** If you are assigned to this group, your treatment will be no different from what you would receive if you were not in the study.

"Standard care" is the recommended treatment a doctor provides for their patients. For dialysis patients, the recommended treatments are frequently described in recognised treatment guidelines.

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

Study Visit

One study visit of approximately 30 minutes (can be carried out *during* your dialysis treatment).

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 target weight, blood pressure and most recent dialysis blood test results. If you have been allocated to the colecalciferol group, your doctor will prescribe this for you and you will be asked to take the first dose as soon as possible after starting the study. For most patients, this will be on the day of agreeing to participate.

Vitamin D blood test

Vitamin D Blood Test (*first 230 patients only*) – Most patients will not have any additional tests while in the study.

If you are one of the first 230 patients in the study, your doctor will inform you of this. You will then have a blood sample taken around four months after starting the study. This will be sent to the research laboratory in Cambridge where it will be tested for vitamin D levels. The result of this test will not be made known to you or your doctor.

What this test involves depends on the kind of dialysis you receive. Every effort will be made to take the sample ***at the same time as your usual dialysis blood tests***. If you have your monthly blood tests taken on dialysis, this will be taken from the dialysis circuit. If you have peritoneal dialysis, your blood test will usually be taken by putting a needle into a vein in your arm. The volume of blood needed for a vitamin D test is very small (approximately 1ml or a quarter of a teaspoon), and can be taken at the same time as your usual blood tests.

Data collection

For all patients, for the duration of the study, we will carry out study assessments via the collection 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 (such as your name, gender, date of birth, and NHS 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 team of researchers directly involved with the study. We will need to retain this data for the duration of the study (8 years) and then archive it for 5 years in accordance with the relevant clinical trial 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) **UK Renal Registry** – your blood test results and other information about you is routinely sent to the UK Renal Registry. This information is usually only used in anonymised form (without identifying you as an individual) to ensure that the care patients at your kidney unit receive is to an acceptable standard. *If you agree to participate in the study, you also agree that we can use this information to find out what happens to your health during the study.* Doing things this way means that we don't have to take any extra blood tests for the study, but can use the results from the tests you have routinely.

b) NHS England – NHS England is the national provider of information on healthcare in the United Kingdom. NHS England collects, stores and analyses information from a variety of sources. If you participate in the study, we will send identifiable data (NHS number, Date of Birth and your initials) to NHS England. NHS England link this information to HES (Hospital Episode Statistics) data which includes information about all hospital admissions. In addition, NHS England hold data on deaths on behalf of the Office for National Statistics (ONS) and will provide the study with date and cause of death which is sourced from civil registration data. NHS England will provide the study with Date of Birth, Postcode, Date and Cause of Death.

a. **Office for National Statistics** – In the unfortunate event that a person dies, this information is obtained from civil registration data by the Office for National Statistics (ONS). 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 on behalf of ONS. This has the added important function of ensuring that we do not direct mail, message or telephone call patients who are no longer alive, potentially causing unnecessary distress to relatives or friends.

b. **Hospital Episode Statistics (HES)** – The NHS collects information on all hospital admissions, including when, why and for how long they happen. In England, this is known as **Hospital Episode Statistics (HES)**. By collecting information from HES, we can tell what happens to the health of participants in the study. For example, if someone suffers a heart attack, this should result in admission to hospital and would show up in the information we collect. By doing things in this way, it means that we can use the information the NHS already holds rather than having to ask patients to attend hospital for regular extra study visits. This is particularly important for patients who need dialysis as their treatment already takes up a lot of their time.

By consenting to this study, you agree that the study team will provide your data to NHS England for linkage to HES data. NHS England will also provide date and cause of death on behalf of ONS.

Equivalent systems to HES exist in Wales (**Patient Episode Database for Wales, PEDW**) and Scotland (**Information Services Division Scotland**, **ISD**). If you live in these areas, the study team will similarly obtain information on hospital admissions from these sources.

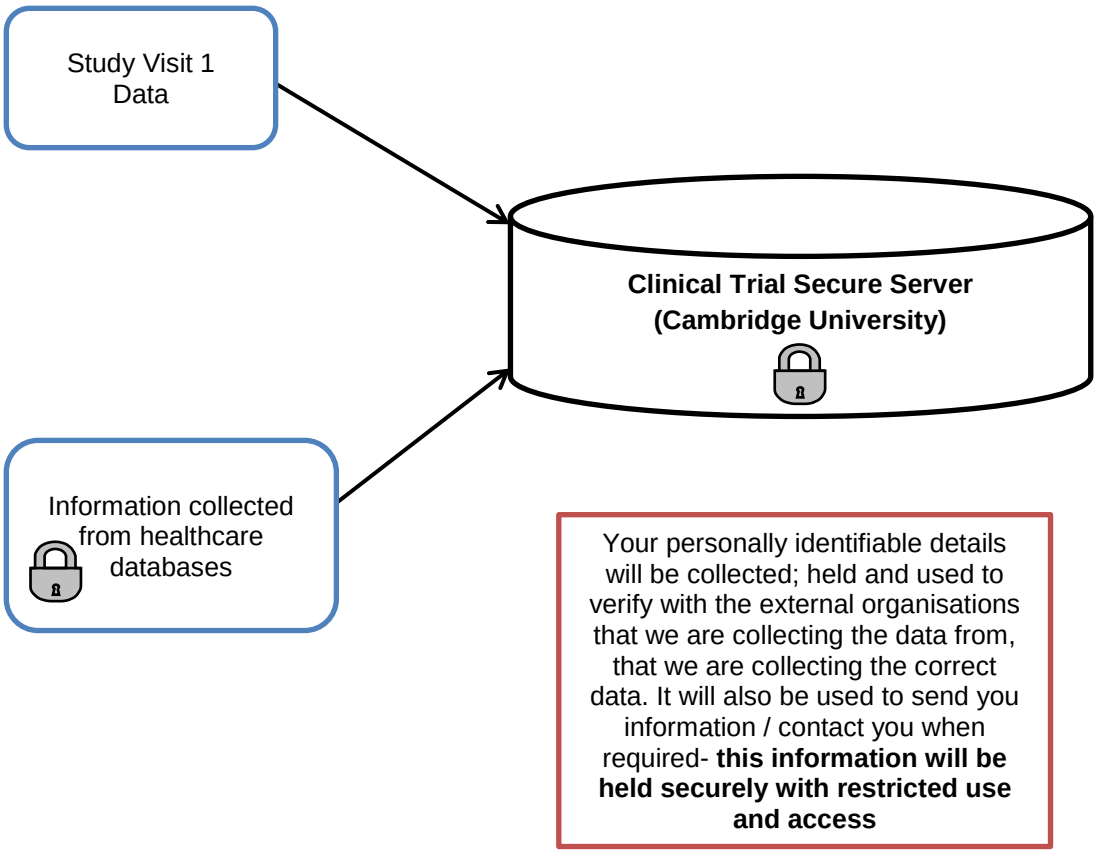
c) **National Cancer Registration and Analysis Service**– if a person develops cancer, this is recorded by the National Cancer Registration and Analysis Service (NCRAS). Usually, this information is analysed anonymously to look at how well we are doing with the battle against cancer. Because it is important for us to see whether Vitamin D has any impact on cancer rates, NHS England will provide the study team with cancer registration data.

Due to the way in which NHS England provides us with data from the Office for National Statistics and National Cancer Registration and Analysis Service, we may receive information about events that occurred before the date you joined the trial, and/or after your withdrawal date (if you choose to withdraw from the trial in the future). Information about events outside of these dates will be deleted upon receipt, and will not be used or shared.

An equivalent cancer registry to the National Cancer Registration and Analysis Service exists in Scotland (The Scottish Cancer Registry through **Information Services Division Scotland**, **ISD**). If you live in Scotland, the study team will similarly obtain information on cancer occurrence from this source.

This study may last for up to 7 years or more. 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.

More information about how your healthcare data will be collected and handled can be found under section 16 of this document. The picture below shows how the information we collect will be kept secure.



6. What will I have to do?

You will need to comply with the following instructions and restrictions as part of your participation in this study:

Medication

It is important that you take the study medication regularly as directed by your study doctor. If you have dialysis at a hospital or satellite dialysis unit, you are likely to be given the colecalciferol when you have your dialysis. If you have dialysis at home, you will need to make sure you keep track of when you need to take the study medication, and ensure that you store it in a cool, dry place. The study app (if you use a smartphone) will send automatic reminders to you when the colecalciferol is due to be taken, and will allow you to tick a box to say that you have taken it.

You should continue using any regular prescription medicine from your GP or dialysis doctor – we will check this list with you prior to starting the study but you **must** inform your study doctor if any changes are made by your GP. You MUST NOT take any additional cholecalciferol as well as the study medication if you are in the cholecalciferol group. Please inform your study doctor immediately if you become aware that another medical practitioner has prescribed you cholecalciferol.

A patient receiving cholecalciferol in the SIMPLIFIED trial also received cholecalciferol from outside of the trial for several months. This meant that they received a double dose of cholecalciferol within this time. They then developed calciphylaxis, which is a serious, uncommon condition in which calcium builds up in small blood vessels of the fat and skin tissues in patients with advanced kidney disease and on dialysis. Calciphylaxis causes

blood clots, painful skin ulcers, may cause serious infection, and can be life threatening. It is possible that the case of calciphylaxis observed in the trial was related to the double dose of cholecalciferol received, although calciphylaxis is a well recognised but rare complication in patients on dialysis not receiving high dose vitamin D supplementation.

Side Effects (also known as adverse events)
Because colecalciferol occurs naturally in the body, side effects are extremely rare. However, you should report any possible side effects of your study participation to the study staff. This includes when you feel unwell or different in any way, regardless of whether you have taken any of the study treatment or not.

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, attend Accident and Emergency or dial 999, as you would under normal circumstances.

Contraception

Men:

If you are male, you will not need to take any special measures.

Women:

Because colecalciferol occurs naturally in the body, it is likely to be safe in pregnancy. However, because no previous studies have used this dose of colecalciferol in pregnancy, we would recommend that you should not participate in this study if you are planning to become pregnant.

Pregnancy is very rare in patients with kidney failure, and women receiving dialysis often do not have a normal monthly cycle. If you menstruate regularly (have regular periods) and are sexually active, and if you have been allocated to the vitamin D group, you should use contraception for as long as you receive the study medicine. If you are uncertain whether this applies to you, please discuss this with your study doctor or nurse.

Women who are able to have a baby must use one of the following, reliable forms of contraception for the entire duration of treatment and for 4 weeks after your last treatment with the study drug:

- Oral contraceptive (either combined or progesterone alone)
- Contraceptive implant, injections or patches
- Vaginal ring
- Intrauterine device (IUD, coil or intrauterine system)
- Condom **and** cap or diaphragm **plus** spermicide (chemical that kills sperm)
- True abstinence where this reflects your usual and preferred lifestyle

You do not need to use contraception if:

- You have only one partner, and the man has had an operation to cut the tubes that carry sperm (vasectomy)
- You are a woman who cannot become pregnant
- You practice true abstinence as part of your usual and preferred lifestyle. If you become sexually active, you must use one of the methods listed above.

If you are a woman and become pregnant during the study, you should inform your study doctor immediately. Your study doctor will discuss all the options available to you. The outcome and progress of any pregnancy would be followed and you would be asked questions about the pregnancy and baby, if appropriate.

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

Colecalciferol is a very safe treatment.

Uncommon side effects (affecting less than 1 in 100 people)

- Too much calcium in your blood (hypercalcaemia). You may feel or be sick, lose your appetite, have constipation, stomach ache, feel very thirsty, have muscle weakness, drowsiness or confusion. Calcium is measured as part of your routine monthly dialysis blood tests, and high calcium is therefore likely to be identified before it makes you unwell.

Rare side effects (affecting fewer than 1 in 1000 people)

- Skin rash
- Itching
- Raised itchy rash (hives)

Tell your study doctor if you experience any of these side effects, or if you notice any side effects not listed.

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

Apart from the blood sample and pregnancy test (if these are applicable to you), all of the study measurements are part of your routine care. The study team don't foresee any risks involved. If you are one of the small number of patients who need an extra blood test for vitamin D, this will be added to your existing blood tests. No additional blood taking procedures are therefore necessary.

The study will take up some of your time, as explained in section 1, point 5 of this document.

9. What are the possible benefits of taking part?

There is no guarantee that you will benefit from taking part in this study. The treatment you receive as part of the study may lead to an improvement in your symptoms and general health, but we cannot predict whether this will be the case. 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?

Most dialysis patients receive pre-activated forms of vitamin D such as alfacalcidol, calcitriol or paricalcitol. If you do not take part in the study, you will continue to receive these treatments as prescribed by your doctor.

11. What happens when the study stops?

At the end of the study your study doctor will discuss with you the current treatment options in terms of vitamin D supplements. Your doctor may ask you to return any unused colecalciferol.

12. Expenses & Payment?

This is a publicly funded study. We are unable to pay you for participating in the study.

We do not anticipate that you will incur any expenses during the study, as no extra visits to your hospital, clinic or dialysis unit are required.

SECTION 2
STUDY 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 get a transplant during the study?

Many patients who take part in the study will receive a kidney transplant while the study is ongoing. Taking part in the study will not jeopardize plans for a kidney transplant, and being on colecalciferol will not be harmful to the new kidney. Indeed, this form of vitamin D may be particularly beneficial.

If you take part in the study and go on to have a transplant, and are in the colecalciferol group, you will no longer be required to take the study medication. We would still collect further follow-up data via linkage on your health until the end of the trial for both the colecalciferol and Standard Care group.

15. What if I decide I no longer wish to participate in the study?

You are free to withdraw from this study at any time without giving a reason and without affecting your future care or medical treatment. If you decide not to participate any further, no more tests will be performed and you will no longer receive the treatment for this study. Any information already provided or results from tests already performed on you or your samples will continue to be used in the study, however no further tests will be performed. Any samples already provided for the study can be destroyed if you wish.

If you withdraw from the study, we would still intend to collect the information from the data sources we will be using to find out more about your health. However, you are also free to withdraw from the data process at any time, in which case no future data will be collected on you from any databases used in the study.

In the unlikely event that you experience serious side effects, which require you to withdraw from the study, your study doctor will follow up with you regarding your progress until the side effect has stabilised or resolved.

16. 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.

In the event that something does go wrong and you are harmed by taking part in this research and this is due to someone's negligence then you may have grounds for legal action for compensation against the 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, and 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 Patient Advice and Liaison Service (PALS) at your hospital.

17. 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 trial based in the United Kingdom. They will be using information from you and your medical records in order to undertake this trial and will act as the data controller for this trial. 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 5 years after the trial has finished to ensure your safety and allow the trial to be reviewed by the authorities after it is finished.

Your rights to access, change or move your information are limited, as the Sponsor organisations 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/patient-privacy-notice/, 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:
Cambridge University Hospitals will collect your name, NHS number and contact details to contact you about this trial, and make sure that relevant information about the trial is recorded for your care, and to oversee the quality of the trial. Individuals from the Sponsors and regulatory organisations may look at your medical and research records to check the accuracy of this trial. Cambridge University Hospitals will pass these details to the Sponsors along with the information collected from you and/or your medical records. The only people in the Sponsor organisations who will have access to information that identifies you will be people who need to contact you in relation to this trial and to audit the data collection process. Cambridge University Hospitals will keep identifiable information about you from this trial for 5 years after the trial has finished.

For participants recruited at other participating sites:
(Add site name) will keep your name, NHS number and contact details to contact you about this trial, and make sure that relevant information about the trial is recorded for your care, and to oversee the quality of the trial. Certain individuals from the Sponsors and regulatory organisations may look at your medical and research records to check the accuracy of this trial.

All information collected about you as a result of your participation in the study will be kept strictly confidential, and will be used for the purposes of this research only. Your

personal and medical information will be kept in a highly secure server within the University of Cambridge and handled securely in accordance with the data protection law(s) to ensure that all information about you is handled in the strictest confidence. 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.

Once you have agreed to participate in this study you will be allocated a unique study number which will be used on all your study documentation. This number will be linked to your personal information; however you will only be identified by this unique number in the final study data. Your consent to the use of study data or your personal data does not have a specific expiry date, but you may withdraw your consent at any time by notifying your study doctor.

By signing the informed consent form, you consent to the study doctor and their staff collecting and using medical and personal data about you for the purposes of the study (study data). This includes: your date of birth, gender, your ethnic origin and personal data about your physical or mental health or condition.
By participating in this study, we will follow your medical status on an on-going basis for the duration of the study. This involves collecting, processing, and transferring your personal data (name, gender, date of birth and NHS number) for medical research purposes only. This will be done by sending the named information to the health records organisations mentioned in section 5. For this process to work, it will involve storing some of your personal data on a secure, password-controlled database with access given to only a very small number of delegated study staff. The various organisations' systems will be asked for information which will then be stored in our highly secure database. In addition, in order for this information to be requested, your study doctor will need to provide the coordinating study centre (Cambridge Clinical Trials Unit at Addenbrooke's Hospital) with some of your personal details.

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 trial data, without any personal information will be published at the end of the trial. At the end of the study, your anonymised study data may be shared with other researchers outside the University of Cambridge, both in the United Kingdom and abroad.

18. What will happen to my samples?

If you are one of the first 230 participants recruited, your blood sample will be sent to a central storage facility at the University of Cambridge. All samples will be stored securely prior to being sent for analysis by an accredited central laboratory approximately one year after the start of the study. The sample will not have any of your personal identifiable information on it, but it will be linked back via your unique study number.

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

The results of the study will be anonymous, and it will be impossible to identify any individual (you) from any of the data produced. When the results of this study are available they will be published in peer reviewed medical journals and used for medical presentations and conferences. They will also be published on the EU Clinical Studies Register website, a central registry for all clinical studies conducted in the EU.

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

20. Who is funding the study?

The study is being funded by that National Institute of Healthcare Research.

21. 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 the East of England – Cambridge East Research Ethics Committee. The Medicines and Healthcare Products Regulatory Agency (MHRA) who are responsible for regulating medicines in the UK have also reviewed this study.

22. 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 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.

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INFORMED CONSENT FORM

Study Title: The SIMPLIFIED Registry Trial

Principal Investigator: **Participant Number:** _____

If you agree with each sentence below, please initial the box		**INITIALS**
1	I have read and understood the Participant Information Sheet version 6.0; dated 06Jun2023 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. 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 SIMPLIFIED study.	
5	I understand that the study team will send my name, NHS number, date of birth and gender to NHS England for linkage with HES data. NHS England will also provide any date and cause of death to the study team on behalf of the Office for National Statistics. I understand that, if I live in Scotland or Wales, this information will be obtained from the equivalent sources described on page 6.	
6	I understand that NHS England will provide the study team with any information on the diagnosis of cancer. I understand that, if I live in Scotland this information will be obtained from the equivalent source described on page 6.	
7	I understand that the study team will send my data to the UK Renal Registry, and that the UK Renal Registry will provide the study team with information about my health.	
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 including using appropriate contraception as listed in Section 1, point 6 of the Participant Information Sheet.	

12	I understand that my blood sample may be sent to a central study laboratory for storage and analysis, if I am one of the first 230 patients enrolled.	
13	I agree to participate in this study.	

_____	_____	_____
Name of patient	Signature	Date
_____	_____	_____
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.

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Survival **Imp**rovement with Colecalciferol in Pat**ie**nts on **D**ialysis

SIMPLIFIED Trial Summary

- The SIMPLIFIED trial aims to determine whether patients on dialysis stay healthier for longer if they take the "**natural**" form of **vitamin D**, called Colecalciferol.

- Natural vitamin D is not usually given to dialysis patients, because doctors used to believe that the body could not use natural vitamin D unless the kidneys were healthy. It turns out that this is not the case: the body does use natural vitamin D even in people who have no kidneys. This is why we now need to test if natural vitamin D is better or worse than the artificial and active forms of vitamin D treatments we currently use.

- The SIMPLIFIED trial is comparing two treatments - **(1)** taking Colecalciferol vs **(2)** Standard care. If you agree to take part, you will be randomly allocated to one of the two groups:

    1) **Colecalciferol group:** If you are assigned to this group you will receive all your usual treatments as recommended by your doctor (*standard care*). In addition, you will be prescribed the study drug, colecalciferol (60,000 IU once every two weeks).

    2) **Standard Care group:** If you are assigned to this group, your treatment will be no different from what you would receive if you were not in the study.

- The SIMPLIFIED trial **does not require any extra hospital visits** or procedures.

- 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.

- The results of this trial will help kidney doctors and nurses to understand whether natural Vitamin D will increase survival in dialysis patients.

- 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