East and North Hertfordshire NHS
NHS Trust

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Participant Information Sheet

Does incremental initiation of haemodialysis preserve native kidney function? A multicentre feasibility randomised controlled trial.

You are being invited to take part in a research study. Before you decide, it is important that you 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, your GP or staff on the Renal Unit if you wish. Ask us if there is anything that is not clear, or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

Patients who start haemodialysis usually retain some natural kidney function for months or years after starting dialysis. Even a small amount of this natural kidney function can be helpful in reducing the need for dietary and fluid restriction. There is also good evidence that retaining a small amount of natural kidney function may provide a survival benefit for patients on dialysis.

Most patients who commence haemodialysis start three times per week for 3.5-4 hours per session, irrespective of the amount of natural kidney function they may have. An alternative approach used in some kidney units is to take account of the natural kidney function in prescribing the amount of dialysis. This may allow patients to start treatment needing to spend less time on dialysis or even to start just twice weekly. The amount of dialysis can be adjusted over time as natural kidney function declines. This is called “incremental haemodialysis”. Both of these approaches are considered to be standard care although it is not known which approach is more beneficial to patients.

There are some suggestions that the frequency of dialysis may influence the rate of decline of natural kidney function but this need to be tested in a large randomised study. To inform the design of such a study, a smaller scale feasibility study is required.

We intend to randomise fifty new starters on haemodialysis with adequate natural kidney function into two groups – a group who will have dialysis prescribed in the standard fashion – three times weekly for 3.5-4 hours per session or a group who will have an incremental start beginning with twice weekly treatment. We will investigate how many patients have sufficient natural kidney function to be eligible, whether patients are willing to participate and continue in the study, compare the rate of loss of kidney function between groups, and ascertain whether this individualised dialysis approach is less intrusive to patients. The results will be used to design a larger definitive study.

Why have I been asked to participate?

You have been invited to participate as you are on a haemodialysis programme within the United Kingdom.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep, and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. This would not affect the standard of care you receive.

What will happen to me if I take part?

If you decide to take part we will need your permission for the local research nurse and consultant nephrologist to look at your medical records. If you are a female of child bearing age we will need to ensure you are not pregnant with a pregnancy test. You will be randomly allocated to one of two study groups. The amount of dialysis you receive (frequency and time) will depend on which study group you are randomised to.
If you are randomised to standard three times a week dialysis (3.5-4h), then you will be requested to have dialysis using that schedule.

If you are randomised to have incremental dialysis, you will dialyse twice weekly initially and afterwards the amount of dialysis you receive will be then adjusted according to the amount of natural kidney function you have. This may mean increasing the amount of time on dialysis up to 4 hours, or increasing to three times a week dialysis during the study.

We will arrange for a blood sample to be taken for the study at the beginning and end of a dialysis session every month with your routine monthly blood tests. The samples will be securely stored in the laboratory for further analysis of blood markers that indicate level of natural kidney function. We will also measure your weight and blood pressure as part of dialysis care. We will ask you to collect all of your urine in a special container between two consecutive dialysis sessions every month.

You will be asked to complete a series of questionnaires in regards to your health and wellbeing before starting the study, visit 6 and end of the study.

We will also monitor you regularly in regards to fluid status, potassium level, dialysis requirements.
During the study we will see you prior to the study and each month to assess your dialysis quality (total of 13 times). We will see you during a dialysis session for your convenience.

What are the possible benefits of taking part?

It is unknown whether dialysis three times a week or in an individualised way (incremental dialysis) is best to preserve natural kidney function and we hope that this study will give us this information. It may be that you are randomised to a study group which benefits you from this perspective but it is not possible to be certain of this. There are no other direct benefits to you of taking part but it is hoped that information we get from this study may help us in the future to improve treatment for patients on dialysis.

What happens when the research study stops?

At the end of the research, your medical care will continue as usual.

What will happen if I don't want to carry on with the study?

You may withdraw from the study at any time, without having to explain why, and we will completely respect your decision. If you withdraw from the study, no other samples will be collected from you and we will not contact you again. Information already collected would be retained and used in the study with your consent. The samples which were already collected and the data collected would be used in the study with your consent. If you wish us not to use the information we will respect it. Your clinical care will not be affected by either taking part or by your withdrawal from the study.

Are there any risks to me?

Only patients with an appropriate natural kidney function are recruited into this study to minimise any potential risks such as inadequate dialysis, fluid overload, and high potassium levels. All recruited participants will be closely monitored at least once a month to check for the above risks. Any concerns from participants or haemodialysis staff will be addressed promptly.

As part of the research study, a small blood sample (~20ml, 4 teaspoons) will be required each month in addition to your routine monthly blood tests and this will be taken from you on dialysis. The amount of blood taken is small and will not have any negative impact on your health**.**

Taking part in the study will not affect your current treatment, nor will it affect your ability to obtain insurance for health purposes or receive a kidney transplant if appropriate.

What will happen to my data that we collect?

Baseline information including age, gender, duration of dialysis and other health information will be collected and your data will then be allocated a unique code that will be anonymous. Medical notes may be looked at by responsible individuals from the Sponsor organisation, the NHS Trust, external researchers from the University of Hertfordshire and from regulatory authorities. During follow up the data will be updated to include any changes in your health such as heart attacks and stroke. At the end of the study your data and any health outcomes will be analysed.

Anonymised study data and files will be stored for the duration of the study and up to 5 years. Your personal data collected by the site, will be stored at the site and archived with other study specific documents for at least 5 years after completion or discontinuation of the study.

If I participate will my personal medical information be kept confidential?

All information that is collected about you during the course of the project will be kept strictly confidential. All collected samples will be identified by a code number only. All data collected as part of the study will be de-identified.

If you consent to take part in the research, some parts of your medical records and any of the information collected about you may be inspected by the sponsor (East and North Hertfordshire NHS Trust). Your records may also be looked at by the regulatory authorities or ethics committees to check that the study is being carried out correctly. All those involved with the study will have a duty of confidentiality to you as a research participant and nothing that could reveal your identity will be disclosed outside of the research team.

What would happen to the results of the research study?

We hope to be able to publish the results of this research and will be happy to provide you with a copy of the publication if you request it. You will not be identifiable in this publication. We will be happy to inform you of the summarised study results by postal letter if you wish to receive it.

Individual data will not be made available to participants unless the results could potentially impact on the individual's clinical care. Results would then be shared with the participant and their dialysis doctor. This decision would be made by the Principal investigator at your hospital.

Will I be paid for taking part in the study?

Participation in this study is voluntary and you will not be paid for taking part.

Will my GP be informed?

Yes, your GP will be informed with your consent that you are involved in this study.

What if new information becomes available?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, the research team will tell you about it and discuss with you whether you want to continue in the study.

Who has reviewed the study?

The study has been reviewed by the East of England – Cambridge South Research Ethics Committee.

Who is organising and funding the research?

This is a multicentre study within the UK funded by The British Renal Society and sponsored by East and North Hertfordshire NHS Trust.

What if something goes wrong?
If you have a concern about any aspect of this study, you should ask to speak with the study doctor/nurse who will do their best to answer your questions.

If you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay your own legal costs. If you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanism will be available to you. Formal complaints should be addressed to:
Mr Nick Carver, Chief Executive, Lister Hospital, Corey's Mill Lane, Stevenage, SG1 4AB (Tel: 01438 314333).

Should you require independent advice about making a complaint or seeking compensation, you may wish to contact the Independent Complaints Advocacy Service (ICAS) for Bedfordshire & Hertfordshire at Pohwer ICAS, Hertlands House, Primett Road, Stevenage, Herts, SG1 3EE. Tel: (0845 456 1082).

Independent information and advice is available from the Patient advice and liaison service (PALS).

Please contact: 01438 284678 or call 01438 314333 and ask to speak to the PALS.

Alternatively please email pals.enh-tr@nhs.net

Contact for Further Information

If you have any problems, concerns, complaints or other questions about this study, you should contact:

Principal Investigator: Dr Raja Mohammed Kaja Kamal on 01438 284346
Chief Investigator: Dr Enric Vilar on 01438 286366
Research Nurses: Ewa Kislowska, Jocelyn Berdeprado on 01438 284346

Emergency 24 hour contact number:

If you need to contact someone outside of normal office hours please call the hospital switchboard on **01438 314 333 and ask to speak to the doctor on-call.**

Thank you very much for taking the time to read this information sheet