Study Title: Colchicine and Dialysis patients – a feasibility study (CAD)

Chief Investigator: Dr Michael Robson, King's College London

You are invited to take part in a research trial. To help you decide whether to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Talk to others about the study if you wish. Contact us if there is anything that is not clear, or if you would like more information. Take time to decide whether you wish to take part.

Brief summary

Colchicine is drug that has been available for decades for the treatment and prevention of gout. Recent studies have shown that colchicine decreases the number of heart attacks and strokes. There are also reasons to believe colchicine may improve outcomes for arteriovenous fistulas and grafts. At present, colchicine is often avoided in dialysis patients due to concerns of accumulation, but this is not based on robust evidence.

We are inviting patients to take part in this study, to assess whether low dose colchicine is tolerated among patients on haemodialysis. If this is confirmed, future studies will assess if colchicine reduces heart attacks/strokes or improves outcomes for arteriovenous fistulas/grafts in patients on haemodialysis.

Why have I been asked to take part?

You have been asked to take part because you are currently on regular haemodialysis and are not already taking colchicine or a drug that may increase colchicine levels.

Do I have to take part?

No, it is up to you to decide whether 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. Deciding not to take part or withdrawing from the study will not affect the healthcare that you receive, or your legal rights.

What would taking part involve?

If you agree to take part in the study, we will ask you to sign a consent form to confirm that you are happy to take part in the study. You will need to take one tablet of colchicine (0.5mg) once a day for 3 months and 2 weeks. After you have entered the study, you will be given packs of colchicine for the whole duration of the study. You will start to take colchicine 2 weeks before your next planned monthly bloods.

You will be interviewed about any side effects 2 days, 2 weeks, then monthly for 3 months after you have started colchicine. This could be done by telephone at a time that is convenient for you or in person when attending haemodialysis.

At the beginning and at the end of the study, you will be asked to complete a survey about your quality of life. These will take you about 10 minutes to fill in. No extra hospital visits will be needed. At the end of study, you will be asked to bring all your used and unused pill packets to help us keep track of how many pills you have taken. With your consent we will send a letter to your GP to let them know that you are taking part in the trial.

Will I be asked to provide any samples?

We will check results from your routine monthly bloods to ensure there are no concerning effects of colchicine. This will not require additional samples or visits.

What are the possible benefits of taking part?

You may not directly benefit from taking part in this study, but the information gained from your participation may help to improve the healthcare of patients in the future. It is possible that colchicine may reduce risks of heart diseases and strokes, but we cannot say this for certain until we have completed this and future studies.

What are the possible disadvantages and risks of taking part?

There might be a risk of experiencing side effects from colchicine. Common side effects may include diarrhoea, nausea, vomiting or stomach discomfort. Rarer side effects include low white blood cell levels, fevers and muscle, liver or nerve problems. The risk of this is very small, and in many of the reports there were other factors contributing to severe side effects, such as use of certain drugs that may interact with colchicine.

Extensive clinical experience has shown colchicine is safe and effective in the general population. At present, there is limited data on the frequency of side effects among patients on haemodialysis. This study has been discussed with the nephrologists and pharmacists in our unit, and they support this study and do not have safety concerns.

The risk of side effects is higher with higher doses of colchicine. We are currently using the lowest dose of colchicine available, which is 3-4 times less than the standard dose used for treating acute gout. The side effects are also reversible once colchicine has been stopped. You will be closely monitored for any side effects through regular blood tests and interviews during the study.

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

You are free to withdraw your consent to participate in the study at any time and without giving a reason. This will not affect the standard of care you receive. Identifiable data already collected would be retained and used in the study. However, you have the right to request samples collected as part of this study to be destroyed and no further laboratory analysis to be performed. Your study doctor can take you out of the study at any time if it is in your best medical interests to stop your participation. The study sponsor also has the right to direct your study doctor to take you out of the study at any time.

What will happen at the end of the study?

The study is expected to take 3 years to complete, starting in 2024. We are hoping to publish the results through medical publications shortly after completing the study. You will not be identifiable in the report. Once your involvement in the study is over, you will continue to receive your usual care. Participants will be informed of the results of the study by email or letter. After the study has ended, data will be stored and retained for 15 years which will include storage at KCL.

What if relevant new information about colchicine becomes available?

Sometimes during a research project, new information becomes available about what is being studied. To ensure your safety, an independent committee of experts will review the results regularly during the study. They will also look at the results of other relevant studies. They can stop the study early if they see any unfavourable results.

If new information becomes available, your study doctor will tell you about it and discuss with you. They will explain to you any potential changes to your normal care and discuss whether you want to, or should, continue in the study. If you decide to continue in the study, you may be asked to sign an updated consent form. If relevant new information becomes available, your study doctor might consider it to be in your best interests for you to withdraw from the study. They will explain the reasons and arrange for your care to continue. If the study is stopped for any other reason, you will be told why, and will receive normal standard of care.

Information on the Use of Data

We may share trial data with researchers or commercial organisations, and they may be outside the UK. The data will be anonymised, and they will not know who the participants are.

How will we use information about you?

We will need to use information from you for this research project. This information will include your initials, NHS number and date of birth. The research team and authorised individuals will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no one can work out that you took part in the study.

As co-Sponsor King's College London has a responsibility to keep information collected about you safe and secure, and to ensure the integrity of research data. Specialist teams within King's College London continually assess and ensure that data is held in the most appropriate and secure way. This may include storage of anonymised or pseudonymised data with a contracted GDPR compliant third-party storage provider within the UK, where they are assessed as the best data storage option. In such cases the third-party storage provider will not have access to any data that could directly identify you.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- Visiting the Health Research Authority website at: www.hra.nhs.uk/information-about-patients/
- Visiting the Guy's and St Thomas' website at: www.guysandstthomas.nhs.uk/research/patients/use-of-data.aspx and King's College London website at: https://www.kcl.ac.uk/research/research-environment/rgei/research-ethics/use-of-personal-data-in-research
- by asking one of the research team (contact details included below)
- by contacting the Data Protection Officer: (For GSTT: Nick Murphy-O'Kane DPO@gstt.nhs.uk; For KCL: Olenka Cogias info-compliance@kcl.ac.uk)

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions [Dr Dorothy Wong, +44 (0)20 7188 3563, dorothy.wong@gstt.nhs.uk]. If you remain unhappy and wish to complain formally, you can do this through the Guy's and St Thomas' Patients Advice and Liaison Service (PALS) on 020 7188 8801, pals@gstt.nhs.uk. The PALS team are based in the main entrance on the ground floor at St Thomas' Hospital and on the ground floor at Guy's Hospital in the Tower Wing.

In the event that something does go wrong and you are harmed during the research you may have grounds for legal action for compensation against Guy's and St Thomas' NHS Foundation Trust and/or King's College London but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

Who is organising the study?

The co-sponsors of the study are King's College London and Guy's and St Thomas' Hospitals NHS Foundation Trust. The sponsors are funding the study.

Who has reviewed the study?

The study has been reviewed by an independent group of people called a Research Ethics Committee, specifically Wales REC 6, to protect your safety, rights, wellbeing and dignity. The study has also been reviewed by at least two independent experts and by the Transplant, Renal and Urology Research Project Board of Guy's Hospital.

Researcher Contact Details:

If you have any further questions about the study please contact Dr Dorothy Wong, +44 (0)20 7188 3563, dorothy.wong@gstt.nhs.uk.

Thank you for taking the time to read this participant information sheet and please keep a copy for your records.