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A study to assess if a large-scale clinical trial giving colchicine to dialysis patients is feasible

Submission date
26/12/2024

Recruitment status
Recruiting

Registration date
15/01/2025

Overall study status
Ongoing

Last Edited
07/04/2026

Condition category
Urological and Genital Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Background and study aims
Colchicine is a 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. Patients on haemodialysis also take a number of medications already and have significant comorbidity. Therefore, it is possible that a higher proportion would have difficulty tolerating colchicine. These concerns mean that a large trial assessing the potential benefits of colchicine in this population cannot begin without further data on feasibility.
This feasibility study will establish whether low-dose colchicine is tolerated and acceptable to dialysis patients and will help us to plan recruitment to future clinical trials. If feasibility is confirmed, there are then strong rationales for large clinical trials exploring the effect of colchicine on both death rates and vascular access outcomes in dialysis patients.

Who can participate?
Patients aged 18 years and over undergoing haemodialysis

What does the study involve?
The researchers will give colchicine 0.5 mg once a day to 100 dialysis patients for 3 months and 2 weeks. They will monitor patients for side effects through regular interviews, and see how many continue to take it for the planned duration. They will check the results from the patients' routine monthly bloods taken on haemodialysis, so no additional blood-taking visits will be needed. At the beginning and the end of the study, patients will be asked to complete a survey about their quality of life.

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

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 the 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. The researchers 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. Patients will be closely monitored for any side effects through regular blood tests and interviews during the study.

Where is the study run from?
Guy's and St Thomas' Hospital NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
October 2024 to November 2027

Who is funding the study?
Guy's and St Thomas' Hospital NHS Foundation Trust (UK)

Who is the main contact?
Dr Dorothy Wong, dorothy.wong@kcl.ac.uk

Contact information

Type(s)
Scientific, Principal investigator

Contact name
Dr Michael Robson

ORCID ID
https://orcid.org/0000-0002-1192-1353

Contact details
Guy's Hospital
Great Maze Pond
London
United Kingdom
SE1 9RT
+44 (0)20 7188 6768
Michael.Robson@kcl.ac.uk

Type(s)
Public

Contact name

Dr Yuen Ting Dorothy Wong

ORCID ID
https://orcid.org/0000-0002-5147-8069

Contact details
Guy's Hospital
Great Maze Pond
London
United Kingdom
SE1 9RT
+44 (0)20 7188 3563
dorothy.wong@kcl.ac.uk

Additional identifiers

Integrated Research Application System (IRAS)
335421

Study information

Scientific Title
Colchicine and dialysis patients; a feasibility study

Acronym
CAD

Study objectives
It is feasible to carry out future definitive full-scale trials of colchicine in patients on haemodialysis based on adherence and recruitment.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 04/11/2024, Wales REC 6 (Floor 4, Institute of Life Science 2, Swansea University, Singleton Park, Swansea, SA2 8PP, United Kingdom; +44 (0)2922940911; Wales.REC6@wales.nhs.uk), ref: 24/WA/0277

Primary study design
Interventional

Study design
Open-label single-centre single-arm feasibility study

Study type(s)
Other

Health condition(s) or problem(s) studied
Haemodialysis

Interventions
Colchicine 0.5 mg once daily orally will be given for 3 months and 2 weeks to all enrolled patients

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Colchicine

Primary outcome(s)
The primary outcome is feasibility and the decision to progress to a full-scale trial based on:
1. Consent rate measured using the number of patients approached, screened, and included in the study over 1.5 years
2. Colchicine continuation rate measured using the number of patients who continued colchicine until the end of the study

Key secondary outcome(s)
1. To demonstrate the feasibility of data collection, including the following:
1.1. Health-related quality of life (QoL) measured using the EQ-5D-5L and vascular access-related QoL measured using the Vascular Access Specific Quality of life measure (VASQol) at baseline and study end
1.2. Vascular access events and interventions (radiological or surgical) measured using data collected in Case Report Forms throughout the study
1.3. Adverse events (including leukopenia, raised CK, gastrointestinal, and neurological) measured using data collected in Case Report Forms throughout the study.
Feasibility will be considered to be demonstrated if complete data is collected for more than 80% of participants for each of the above outcomes.
2. To establish the utility of the EHR (electronic health records), a dataset from the EHR will be extracted and compared to the data entered into the eCRF database at the end of the study.

Completion date
01/11/2027

Eligibility

Key inclusion criteria
1. Anyone who is undergoing haemodialysis
2. Aged 18 years or over
3. Able to give informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Already taking colchicine for a clinical indication.
2. Taking a drug known to increase colchicine levels.
3. Has a previously documented intolerance of or allergy to colchicine
4. Has a history of chronic liver disease, or abnormal liver function (i.e. ALT > 1.5 x upper limit of normal). Patients with a history of hepatitis are eligible provided these limits are not exceeded.

Date of first enrolment
01/04/2025

Date of final enrolment
31/12/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Guy's and St Thomas' Hospitals
Trust Offices
Guy's Hospital
Great Maze Pond
London
England
SE1 9RT

Sponsor information

Organisation
King's College London

ROR
https://ror.org/0220mzb33

Organisation
Guy's Hospital

ROR
https://ror.org/04r33pf22

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Guy's and St Thomas' NHS Foundation Trust

Alternative Name(s)

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Pseudonymised clinical and research data for the study will be stored on an electronic database (REDCap). All requests for access to the data entry system must be authorised by the Chief Investigator. All requests for data exports must be authorised by the trial statistician. Following the completion of the trial all documentation and trial data will be kept for at least 15 years.

The datasets generated during and/or analysed during the current study will be available upon request from Dr Michael Robson (michael.robson@kcl.ac.uk).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		01/04/2026	07/04/2026	Yes	No
Participant information sheet	version 2	20/11/2024	03/01/2025	No	Yes