CKD FIX Trial

Inclusion Criteria

To be eligible to participate in this trial, participants need to satisfy ALL of these inclusion criteria:

1) Adult (age ≥ 18 years),
2) CKD stage 3 or 4 (eGFR 15 to 59 mL/min/1.73 m2 inclusive),
3) Random urine albumin to creatinine ratio ≥ 30 mg/mmol

OR
Evidence of progression of CKD (decrease in eGFR ≥ 3.0 mL/min/1.73 m2 in the preceding ≤ 12 months, calculated as the difference between the first and last tests, based on minimum of 3 blood tests with each test done at least 4 weeks apart).

NOTE: For the diagnosis of CKD and determination of eGFR decline, eGFR estimated by either MDRD or CKD-EPI equation can be used according to the local practice.

Exclusion Criteria

Potential participants must have NONE of the following exclusion criteria:

1) Past history of clinically established gout,
2) History of hypersensitivity to allopurinol,
3) Kidney transplant recipients,
4) Concurrent treatment with azathioprine, 6-mercaptopurine, theophylline, cyclophosphamide, cyclosporine, probenecid, phenytoin, or chlorpropamide,
5) Indication for allopurinol, including history of frequent attacks of gout, tophus or tophi on clinical examination or imaging study , uric acid nephropathy, uric acid nephrolithiasis or urolithiasis,
6) Current non-skin cancer malignancy,
7) Unresolved acute kidney injury in last 3 months,
8) Current pregnancy, breast feeding,
9) Any uncontrolled psychological illness or condition which interferes with their ability to understand or comply with the requirements of the study,
10) Elective or imminent initiation of maintenance dialysis or kidney transplantation expected in the next 6 months.

2.3 Concurrent treatments

2.3.1 Current allopurinol use
If a patient is currently taking allopurinol for asymptomatic hyperuricaemia, they may be considered for entry into the study provided their treating physician agrees to cessation of the drug. In this instance a washout period of 14 days prior to randomisation will apply.

2.3.2 Concurrent use of colchicine
Provided there has not been a previous clinical diagnosis of gout, a participant may enter the study with the concomitant use of colchicine at the treating physician's discretion. However, there is no evidence to recommend colchicine as a preventative measure against a gout attack when initiating uric acid-lowering therapy with allopurinol in people who don't have a history or clinical evidence of acute or chronic gout. Therefore, it is not necessary to prescribe colchicine in this study.
If there is a requirement for a participant to commence colchicine during the course of the study, the study medication should be stopped. Recommencement of study medication will be at the treating physician's discretion and will be managed as outlined in section 3.1.3.