

Progress Report: Sri Lanka Clinical Trials Registry

SLCTR registration number: **SLCTR/2017/026**

Scientific title of trial: **Open label randomized controlled clinical trial to study the effects of achieving lowered uric acid targets with Allopurinol on rate of progression, cardiovascular morbidity and inflammatory markers of Chronic Kidney Disease of uncertain etiology (CKD-u) Sri Lanka**

Date of commencement (enrolment of first participant): 15/12/2017

Progression: 6 months 1 year 2 years 3 years
At completion

1. Baseline data

Any changes to the trial design/ methodology/ protocol after commencement: Yes

Inclusion criteria-

- eGFR equal or less than 60ml/min/1.73m² and more than 10 ml/min/1.73m²
- Age 21-75 years

Serum bicarbonate and urine PH was included to identify any associations with renal tubular dysfunction. There were several technical issues as well as patient compliance issues due to complicated sample collection protocol and urine volumes. Both were abandoned and very unlikely to have an impact on outcome.

HsCRP was steady during the first year of follow up and not required to check frequently. Accordingly it has been changed to annual assessment.

Any changes to trial outcomes after commencement: No

2. Current status

Recruitment status: **recruitment completed; follow-up completed up to 24 months**

Number assessed for eligibility: 1552

Number recruited and allocated/randomized: 398 probable and confirmed CKDu patients

Number allocated/randomized to each intervention/arm (please edit as relevant):

Arm 1 (Allopurinol Treatment arm): 199

Arm 2 (Control arm): 199

Losses/exclusions after allocation/randomization (please edit as relevant): 60

Arm 1 (Allopurinol Treatment arm): 30

Arm 2 (Control arm): 30

3. Trial output

Date of trial completion ("last patient, last visit"): Intervention is still continuing

Final sample size: 338

Arm 1 (Allopurinol Treatment arm): 169

Arm 2 (Control arm): 169

Summary of Interim/Final data (if available):

Data analysis is on progression

Abstract presentations of results at scientific meetings


Note: please include a URL link or scanned copy of the abstract

Title of Abstract	Full citation (please include authors, date, title of conference and place of presentation, page number of abstract).
Effect of lowering uric acid with allopurinol on disease progression in CKDu: an interim analysis	Hettiarachchi T.W , Sudeshika S.H.T, Madushan K.P.S, Elladeniya N.C, Wijetunge S, Abeyesundara H.T.K, Nanayakkara N;Kandy Society of Medicine 41 th Annual Academic Session 2019; page 29 (Annexed scan copy)

Publications

Note: please include a URL link or scanned copy of the publication

Title of paper	Full citation (please include authors, title of journal, volume, issue and page numbers, and/or DOI)


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Date: 2020/01/12