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):

Progression: 6 months □

1 year √

2 years □

3 years □

At completion □

1. Baseline data

Date of commencement: 15/12/2017

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

Changes: Inclusion criteria-

• eGFR equal or less than 60ml/min/1.73m² and more than 10 ml/min/1.73m²

Age 21-75 years

Any changes to trial outcomes after commencement: No

2. Current status

Recruitment status: recruitment complete; follow-up completed up to 12 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):

Allopurinol treatment arm: 199

Control arm: 199

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

Allopurinol treatment arm: 25

Control arm: 29

3. Trial output

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

Final sample size: 344

Arm 1 (Allopurinol Treatment arm): 174

Arm 2 (Control arm): 170

Summary of Interim/Final data (if available):

Data Analysis in progress			

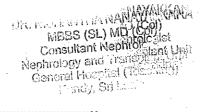
Abstract presentations of results at scientific meetings Note: please include a URL link or scanned copy of the abstract

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

Date:09/01/2020