## **Progress Report: Sri Lanka Clinical Trials Registry**

SLCTR registration number: SLCTF	R/2015/30			
Scientific title of trial: A study to assess the improvement of management outcomes in Chronic Kidney Disease of Uncertain etiology by introducing clinical pharmacy services to selected out-patient renal clinics in the North Central Province, Sri Lanka				
Date of commencement (enrolment of first participant):05/01/2016				
Progression: 6 months □	1 year □	2 years □		
3 years $\square$ At completion $\square$				
One year and nine months after commencement				

## 1. Baseline data

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

previous	Current
The study subjects will be recruited from the patients diagnosed with CKDu Stages 3 and 4, attending out-patient renal clinics in Teaching Hospital, Anuradhapura, General Hospital, Polonnaruwa and District Hospital, Medawachchiya	The study subjects will be recruited from the patients diagnosed with CKDu Stages 4 and 5, attending out-patient renal clinics in Teaching Hospital, Anuradhapura  (But not in General Hospital, Polonnaruwaand District Hospital, Medawachchiya)
Individualized patient counseling on proper use of drugs for 15 minutes. Same intervention will be done over a period of one year ( at recruitment and 3,6 and 9 months)	Individualized patient counseling on proper use of drugs for 15 minutes. Same intervention will be done over a period of one year ( at recruitment and 2,6 and 10 months)

Any changes to trial outcomes after commencement:

Previous	Current
Quality of life was the primary outcome	Quality of life is a secondary outcome
Drug adherence was a secondary outcome	It was changed to the primary outcome assessed by a validated questionnaire. Svarstad, B.L., Chewning, B.A., Sleath, B.L., Claesson, C. (1999) The brief medication questionnaire: A tool for

screening patient adherence and barriers
to adherence. Patient Education and Counseling, 37:113-124

## 2. Current status

Recruitment status: recruitment complete (but still continuing the 4<sup>th</sup> follow ups and final data collection)

Number assessed for eligibility:

Number recruited and randomized: 257 patients

Number allocated to each intervention/arm: 127 patients for control arm and 129 patients for intervention arm

Losses/exclusions after randomization: One patient was excluded after allocation and 2 patients defaulted from the study.

## 3. Trial output

Summary of Interim/Final data (if available):

First, second and third follow ups were done for all the recruited patients. Fourth follow up and final data collection is still ongoing.

Three patients have undergone dialysis and two patients havedied in intervention arm up to this pint.

Four patientshave undergone dialysis and three patients have died in the control arm up to this point.

Presentations of results at scientific meetings:

(Please attach a scanned copy or link to abstract)

Publications:

(Please attach a scanned copy or link to paper)

N.D.D Wickramasinghe	
Name and signature of Responsible Registrant/	Date: 03/10/2017