

Progress Report: Sri Lanka Clinical Trials Registry

SLCTR registration number: SLCTR/2014/007

Scientific title of trial: Double blind randomized placebo controlled trial of corticosteroids and doxycycline in the treatment of interstitial nephritis.

Date of commencement (enrolment of first participant): 20/04/2014

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

1. Baseline data

Any changes to the trial design/ methodology/ protocol after commencement: NO

Any changes to trial outcomes after commencement: YES, proteinuria disappearance was added as secondary outcomes.

2. Current status

Recruitment status: ~~pending/ recruiting/ recruitment complete/ recruitment suspended / recruitment terminated~~

Number assessed for eligibility: 70

Number recruited and randomized: 59

Number allocated to each intervention/arm: 16,14,13 and 16

Losses/exclusions after randomization: 10

3. Trial output

Summary of Interim/~~Final~~ data (if available):

Seventy symptomatic previously healthy individuals from CKDu endemic regions who full filled inclusion criteria were recruited for biopsy. After histological confirmation of Interstitial Nephritis, 59 patients were randomized into four groups. 15 patients into Group 1 (prednisolone + placebo), 12 to group 2 (doxycycline + placebo), 10 to group 3 (prednisolone + doxycycline), and 12 to group 4 (two placebos) had completed a course of six months treatment. Analysis at the end of six months, statistically significant serial reduction in mean serum creatinine was observed in steroid treated group 1 (P 0.001). There was no statistically significant difference in serial proteinuria disappearance from baseline to 6th months, in all four groups. The kidney BPL >1cm shrinkage is observed in group 2 and group 4 [P values 0.01, 0.004 and 0.038 left & right kidneys in Gp2 and right kidney in Gp4 respectively].

Presentations of results at scientific meetings: Abstract presentation

At World Congress of Nephrologists WCN 2015, in Cape town, South Africa, 13-17 March 2015.

<http://www.satellite2015.ckhdp.org/abstracts.php>

106 (0223). CKDU SRI LANKA IS A POSSIBLE SEQUELE OF INTERSTITIAL NEPHRITIS! CLINICO - PATHOLOGICAL PROFILE OF SYMPTOMATIC NEWLY DIAGNOSED CKDu PATIENTS (POSTER AND FREE COMMUNICATION)

M.Z. Badurdeen¹, N. Nanayakkara², A.W.M. Wazi^{1,2}, N.V.I. Ranathnatinga¹, D.T.D.J. Abeysekara¹, P. Rajakrishna², J. Thinnaratchi², P.V.R. Kumarasiri¹, D.M.S.D.K.D. Welagedera², R.M.N.N. Rajapaksha², A.P. De Alwis²

1. Faculty of Medicine, University of Peradeniya, Peradeniya, Central Province, Sri Lanka,
2. Renal Transplant and Dialysis Unit, Teaching Hospital Kandy, Kandy, Central Province, Sri Lanka

zeid1964@gmail.com

Introduction: Majority of published data on Chronic Kidney Disease of Uncertain etiology (CKDu) is on asymptomatic patients who were detected in screening programs. It is important to understand the early pathophysiological changes to identify possible etiology and progression of the disease. CKDu pathology is a Tubule-Interstitial Nephritis (TIN).

Objective: This study is designed to describe clinico-pathological profile of symptomatic CKDu patients with elevated serum creatinine.

Method: More than ten years aged symptomatic patients with two elevated serum creatinine in three months' period from known CKDu regions in Sri Lanka were included. All other causes of CKD were excluded with history and biochemical testing. Normal size kidneys were biopsied. Histological evidence of immune complex mediated disease and other identifiable primary or secondary renal disease were excluded. The renal lesions were scored semi quantitatively as 0, 1,2,3, if there were no lesion, upto30% a, 30-60%, and >60% area affected respectively. The disease activity index was scored as a sum of tubulitis and interstitial inflammation (0-6) and chronicity index as a sum of glomerular sclerosis, tubular atrophy, interstitial fibrosis and peri-glomerular fibrosis (0-12).

Results: Fifty-nine patients had fulfilled the inclusion criteria. The mean age was 44.27(8.91) and male to female ratio 55:4. There were 57 farmers and 2 engaged in other occupations. The presenting month of patients were 32.2% in October to April and 67.8% in May to September in "Maha" & "yala" seasons of dry zone respectively. 98% of patients were in stage 2 to 4 of CKD. Backache 42, Feverish Fatigue feeling 37, Dysuria 23, Joint pain 22, and Dyspepsia 9 were presenting symptoms. The mean serum creatinine at biopsy was 143.86(47.91) Mmol/L. Urine protein 62.8%, RBC 79.3% and puss cells 48.6% were positive. The mean ESR 33.72 (23.18) mm/Hr and serum calcium 2.37(0.24) mmol/L were high. Mean Hb%, serum protein, phosphate, and uric acid were normal. Lymphocyte infiltration 98.3%, Tubulitis 81.4%, Glomerular sclerosis 81.4%, interstitial fibrosis 88.1%, Tubular atrophy 93.2%, Peri-Glomerular fibrosis 42.4% were the salient histological lesions. The Mean activity index and chronicity index 3.23(1.8), 4.83(2.14) respectively.

Conclusion: The initial presentation of CKDu is predominant in middle aged male farmer with acute symptoms like feverish fatigue feeling with backache, joint pain, dysuria and majority present in May to September of the "Yala" season in the endemic regions of the dry zone in Sri Lanka. The biochemical profile of acute CKDu is positive urine proteins, Rbc and puss cells with elevated inflammatory markers. The CKDu is a tubule interstitial nephritis having active & chronic lesions together. The Pathological profile has activity with Tubulitis, Lymphocyte infiltration and chronicity with Glomerular sclerosis, Tubular atrophy, interstitial fibrosis and Peri- Glomerular fibrosis.

(Please attach a scanned copy or link to abstract)

Publications: NO

(Please attach a scanned copy or link to paper)

A handwritten signature in blue ink, appearing to be 'N. Nanayakkara', written on a light blue background.

Dr. Nishantha Nanayakkara

Date: 28th of April 2016

(Name and signature of Responsible Registrant)