Sri Lanka Clinical Trials Registry
Progress Report

Trial registration Number: SLCTR/2015/010

Title of the trial: Tolerability and effectiveness of every-other-day atorvastatin dosing in patients with statin related muscle disease: a randomized controlled clinical trial

Time period covered by the progress report: from 01.01.2017 to 31.12.2017

1. **Date of commencing research activities**: 25.05.2015
2. **Institution / setting where the research is carried out**: Colombo South Teaching Hospital and University of Sri Jayewardenepura
3. **Brief description of research activities carried out during the period under review**:

   3.1 State of the study: recruiting
   3.2 Details :

	01.01.2017 to 31.12.2017	Total from 25.05.2015 to 31.12.2017
Number recruited	**33**	94
Number screened	**610**	1805
Screen failures	**577**	1711
Number completed trial	**38**	85
Lost to follow up	**0**	02

4. **Presentations / Publications / Communications arising from the trial during the project report period covered** :

i. Wijekoon CN, Wijekoon PWMCSB, Sumanadasa S, Bulugahapitiya U, Wijayawardena S, Pathirana N, Samarasinghe M, Senarath U. Statin-related muscle disease in clinical practice: a descriptive study in a group of Sri Lankan patients. Proceedings of the 129th Anniversary International Medical Congress of the Sri Lanka Medical Association, July 2016:102-103 (OP 002)

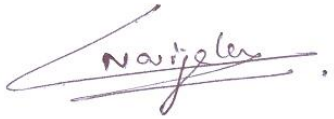
ii. Wijekoon CN, Wijekoon PWMCSB, Wickramasinghe MC, Paranavitane SA, Kottage A, Sumanadasa S, Bulugahapitiya U, Senarath U. Risk factors for muscular symptoms associated with atorvastatin therapy: evidence from an observational study in a group of Sri Lankan patients. Proceedings of the 49th Annual Academic Sessions of Ceylon College of Physicians; September 2016: 112 (PP 29)

5. **Is the work on schedule?** Originally expected number of patients recruited to the trial by the end of 2 ½ years was 125. However only 94 have been recruited as there was a lack of eligible patients in the study sites and resource limitations (mainly availability of research coordinators) restrict expansion of the trial to other sites.

6. **Is there any significant deviation from the original work plan**? No

7. **Brief work plan for the next 12 months:**

   Screening of patients will be continued in order to select the patients eligible for the clinical trial. Due to logistic reasons (i.e. limited number of eligible patients for recruitment at the current study site and inability to expand to other study sites due to lack of human resources) we plan to finish recruitment once the total number of patients recruited to this exploratory trial reaches 100-110 which is expected to be done over the next 2-3 months. All recruited patients will be followed up monthly and trial outcomes will be assessed at 3 months and 6 months following recruitment. We plan to do scientific presentations and write research articles based on the data collected.



Dr. CN Wijekoon (Principal Investigator) Date: 08.01.2017