Sri Lanka Clinical Trials Registry Final 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 25.05.2015 to 31.12.2018

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: Trial completed

3.2 Details:

	25.05.2015 to 31.12.2018
Number recruited	101
Number screened	1822
Screen failures	1721
Number completed trial	99
Lost to follow up	02

4. Presentations / Publications / Communications arising from the trial :

- 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)
- iii. Wijekoon CN, Wijekoon PWMCSB, Bulugahapitiya U, Pathirana N, Wickramasinghe MC, Paranavitane SA, Kottage A, Wijayawardena S, Karunarathne M, Samarasinghe M, Sumanadasa S, Herath Y. Effectiveness of every-other-day atorvastatin dosing in patients with statin-related muscle disease: a randomised controlled clinical trial. Under review for presentation at 132nd Anniversary International Medical Congress of the Sri Lanka Medical Association, July 2019

Further conference communications are planned. The manuscript of a full paper is also almost ready for submission to an indexed journal.

5. Conclusions:

This exploratory trial was completed successfully even though the expected number of patients (150) could not be recruited 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). The follow up rate and the study completion rate of the recruited patients were highly satisfactory.

Date: 31.12.2018

Dr. CN Wijekoon (Principal Investigator)

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