

Progress Report: Sri Lanka Clinical Trials Registry

SLCTR registration number: SLCTR/2013/034

Scientific title of trial: A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Effect of Alirocumab(SAR236553/REGN727) on the Occurrence of Cardiovascular Events in Patients Who Have Recently Experienced an Acute Coronary Syndrome

Date of commencement (enrolment of first participant): 1st patient was screened on 30 December 2013

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

1. Baseline data

Date of commencement: 28 November 2013. In the previous progress report it has been erroneously mentioned as 22 Nov 2013.

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

- Amended Clinical Trial Protocol 6 version 2.0 dated 05-Dec-2013
- Amended Clinical trial Protocol 8 version 1.0 dated 16 Apr 2015
- Amended Clinical trial Protocol 11 version 1.0 dated 25 Feb 2016

Any changes to trial outcomes after commencement: No

2. Current status

Recruitment status: Recruitment completed

Number assessed for eligibility: 689

Number recruited and randomized: 314

Number allocated to each intervention/arm: Double Blinded

Losses/exclusions after randomization (as of 10 Nov 2017):

Temporary end of treatment- 06

Permanent end of treatment- 43

3. Trial output

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

Presentations of results at scientific meetings: No

Publications: No

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Date: ¹⁴ ~~24~~ / NOV / 17