

# Progress Report: Sri Lanka Clinical Trials Registry

---

SLCTR registration number: SLCTR/2014/036

Scientific title of trial: A Phase III, Multicenter, Double-Blind, Randomized, Placebo-Controlled Clinical Trial to Evaluate the Safety and Efficacy MK-0431A (A Fixed-Dose Combination Tablet of Sitagliptin and Metformin) in Pediatric Patients with Type 2 Diabetes Mellitus With Inadequate Glycemic Control on Metformin Therapy (Alone or in Combination with Insulin)

Date of commencement (enrolment of first participant):

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

---

## 1. Baseline data

Any changes to the trial design/ methodology/ protocol after commencement: Yes  
Note: Respective amendments were notified to NMRA and Approval take from ERC

Any changes to trial outcomes after commencement: No

## 2. Current status

Recruitment status: recruitment completed

Number assessed for eligibility: 27

Number recruited and allocated/randomized: 14

Number allocated/randomized to each intervention/arm (please edit as relevant): Double blind study

Losses/exclusions after allocation/randomization (please edit as relevant): 02

## 3. Trial output

Date of trial completion ("last patient, last visit"): Not available

Final sample size: 133 randomized

Summary of Interim/Final data (if available):

Not applicable
----------------

Abstract presentations of results at scientific meetings

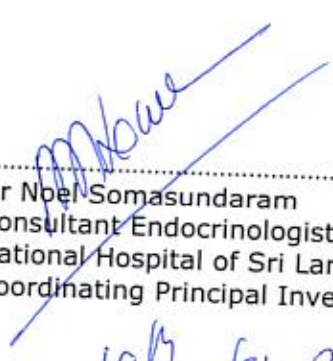
Note: please include a URL link or scanned copy of the abstract

Title of Abstract	Full citation (please include authors, date, title of conference and place of presentation, page number of abstract).
Not applicable	

Publications

Note: please include a URL link or scanned copy of the publication

Title of paper	Full citation (please include authors, title of journal, volume, issue and page numbers, and/or DOI)
Not applicable	

  
.....  
Dr Noel Somasundaram  
Consultant Endocrinologist  
National Hospital of Sri Lanka  
Coordinating Principal Investigator

DR. NOEL SOMASUNDARAM  
MBBS, MD, MRCP  
Consultant Endocrinologist  
National Hospital of Sri Lanka

.....  
Date

19<sup>th</sup> Sep 2015