

Progress Report: Sri Lanka Clinical Trials Registry

SLCTR registration number: SLCTR/2014/037

Scientific title of trial: A Phase III Multicenter, Double-Blind, Randomized, Placebo-Controlled Clinical Trial to Evaluate the Safety and Efficacy of MK-0431A XR (a Fixed-Dose Combination Tablet of Sitagliptin and Extended-Release 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): 05 Jan 2015

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

1. Baseline data

Any changes to the trial design/ methodology/ protocol after commencement: Yes, Respective amendments were notified to NMRA and approval taken from ERC

Any changes to trial outcomes after commencement: No

2. Current status

Recruitment status: recruitment completed

Number assessed for eligibility: 21

Number recruited and allocated/randomized: 09

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

Losses/exclusions after allocation/randomization (please edit as relevant): 01

3. Trial output

Date of trial completion ("last patient, last visit"): 15-Sep-2019

Final sample size: 101 Randomised

Summary of Interim/Final data (if available):

Not Available

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 available	

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 available	

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