

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): 30-Dec-2014

Progression: 6 months 1 year 2 years **x** 3 years

At completion

1. Baseline data

Date of commencement: 30-Dec-2014

Any changes to the trial design/ methodology/ protocol after commencement: Yes.
Protocol amendment 11 and 12.

Any changes to trial outcomes after commencement: No

2. Current status

Recruitment status: recruiting

Number assessed for eligibility: Screened patients in Sri Lanka – 22

Number recruited and randomized: Randomized patients in Sri Lanka – 12

Number allocated to each intervention/arm: Double-blind study

Losses/exclusions after randomization: Discontinued patients in Sri Lanka – 02

3. Trial output

Summary of Interim/Final data (if available): Not available

Presentations of results at scientific meetings: Not available

Publications: Not available

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Date