

## Progress Report: Sri Lanka Clinical Trials Registry

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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   
At completion

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### 1. Baseline data

Date of commencement: Jan 2015

Any changes to the trial design/ methodology/ protocol after commencement: Yes.  
Information updated in protocol amendment sheet separately.

Any changes to trial outcomes after commencement: No

### 2. Current status

Recruitment status: / recruiting/

Number assessed for eligibility: Screened patients in Sri Lanka – 13  
Screened patients in study – 103

Number recruited and randomized: Randomized patients in Sri Lanka – 05  
Randomized patients in study – 41

Number allocated to each intervention/arm: Double-Blinded study.

Losses/exclusions after randomization: Discontinued patients in Sri Lanka – 00  
Discontinued patients in study – 08

### 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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