

Progress Report: Sri Lanka Clinical Trials Registry

SLCTR registration number: SLCTR/2011/008

Scientific title of trial: A Phase III, multicentre, international, randomised, parallel group, double blind cardiovascular safety study of BI 10773 (10 mg and 25 mg administered orally once daily) compared to usual care in type 2 diabetes mellitus patients with increased cardiovascular risk

Date of commencement (enrolment of first participant):

Progression: 6 months 1 year 2 years 3 years

At completion x

1. Baseline data

Date of commencement: First subject was randomized on 30 May 2011

Any changes to the trial design/ methodology/ protocol after commencement: No

Any changes to trial outcomes after commencement: No

2. Current status

Recruitment status: Recruitment completed

Number assessed for eligibility: 113

Number recruited and randomized: 63

Number allocated to each intervention/arm: Not Applicable [It was a double blinded study]

Losses/exclusions after randomization: 1

3. Trial output

Summary of Interim/Final data (if available): Please find CSR attached

Presentations of results at scientific meetings: Not Applicable

Publications: Not Applicable

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Coordinating Principal Investigator

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