Progress Report: Sri Lanka Clinical Trials Registry

SLCTR registration number: SLCTR/2014/002

Scientific title of trial: MRZ 60201_3074_1: Prospective, double-blind, placebo-controlled, randomized, parallel-group, multi-center study with an open-label extension period to investigate the efficacy and safety of two different doses of NT 201 in Botulinum toxin treatment-naïve subjects with blepharospasm

Date of commencement (enrolment of first participant):

Progression: 6 months 1 year 2 years × 3 years

At completion

1. Baseline data

Date of commencement: 02 December 2013

Any changes to the trial design/ methodology/ protocol after commencement: Yes. Protocol version 1.0, final dated 04 May 2015

Any changes to trial outcomes after commencement: No

2. Current status

Recruitment status: Recruiting

Number assessed for eligibility: Screened subjects from Sri Lanka: 24 Screened subjects from the study: 49

Number recruited and randomized: Randomized subjects from Sri Lanka 23 Randomized subjects from the study: 46

Number allocated to each intervention/arm: Double blind

Losses/exclusions after randomization: None

3. Trial output

Summary of Interim/Final data (if available): Not available yet as study is still on going

Presentations of results at scientific meetings: Not conducted yet, as study is still ongoing.

Publications:None

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Date: 70 Oct 2015