

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): 21 Jan 2014

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
MRZ60201_3074_1 Version 6.0 final (12-NOV-2015)

Any changes to trial outcomes after commencement: No

2. Current status

Recruitment status: Sri Lanka: Last patient completed on 05 Jul 2016

Number assessed for eligibility: Screened subjects from Sri Lanka - 34

Number recruited and randomized: Randomized subjects from Sri Lanka - 30

Number allocated to each intervention/arm: Double-blind

Losses/exclusions after randomization: 4 patients prematurely ended the study participation

3. Trial output

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

Presentations of results at scientific meetings: NA

Publications: NA

B. Senanayake

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Dr. Bimasara Senanayake
Consultant Neurologist
Colombo South Teaching Hospital
Kalubowila