

Progress Report: Sri Lanka Clinical Trials Registry

SLCTR registration number: SLCTR/2014/017

Scientific title of trial: A Phase III, Open-label, Randomized, Multi-center Study of the Effects of Leukocyte Interleukin, Injection [Multikine] Plus Standard of Care (Surgery + Radiotherapy or Surgery + Concurrent Chemoradiotherapy) in Subjects with Advanced Primary Squamous Cell Carcinoma of the Oral Cavity / Soft Palate Versus Standard of Care Only

Date of commencement (enrolment of first participant): 17/Dec/2014

Progression: 6 months 1 year 2 years 3 years
5 years At completion

1. Baseline data

Any changes to the trial design/ methodology/ protocol after commencement: None

Any changes to trial outcomes after commencement: Yes. Protocol amendment 03
Version 4.0 dated 27 June 2014

2. Current status

Recruitment status: pending/ recruiting/ **recruitment complete**/ recruitment suspended / recruitment terminated

Number assessed for eligibility: 97

Number recruited and allocated/randomized: 46

Number allocated/randomized to each intervention/arm (please edit as relevant):

Group A:20

Group B:7

Group C:19

Losses/exclusions after allocation/randomization (please edit as relevant):

Group A:4

Group B:1

Group C:5

3. Trial output

Date of trial completion ("last patient, last visit"): 29 Nov 2019

Final sample size: 46

Summary of Interim/Final data (if available):

N/A

Abstract presentations of results at scientific meetings
Note: please include a URL link or scanned copy of the abstract

Title of Abstract	Full citation (please include authors, date, title of conference and place of presentation, page number of abstract).
N/A	N/A
N/A	N/A

Publications
Note: please include a URL link or scanned copy of the publication

Title of paper	Full citation (please include authors, title of journal, volume, issue and page numbers, and/or DOI)
N/A	N/A
N/A	N/A



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Dr Prasad Abeyasinghe
Co-ordinating Principal Investigator

Date: 28 Aug 2019