

Interim Report March 2015

The Comparison of Toxicity Between Weekly and Three-Weekly Cisplatin Infusion in Chemo-radiation for Squamous Cell Carcinoma of Head and Neck

Introduction

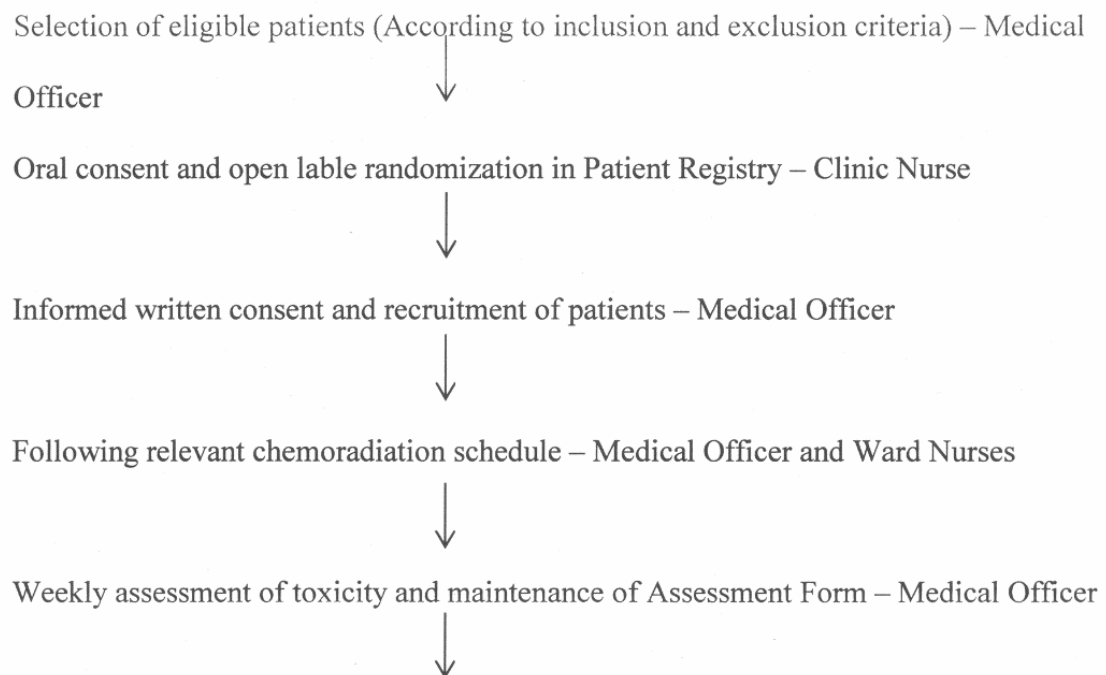
We have received Ethical Committee clearance in July 2014 and Sri Lanka Clinical Trial Registration on 22nd September 2014. Accordingly we have started our research on 22nd September 2014.

First we have recruited 12 patients for the Pilot study. Radiation dose administered to the primary and neck was between 66 and 70 Gy and administered as fractions of two Gy for five days a week. The patients were randomly divided into two groups based on their chemotherapy regimens. The patients who were treated with weekly cisplatin (40 mg/m²/week) during radiotherapy were the group A, while the patients who were treated with standard regimen (80 mg/m²/cycle, every 21 days) were group B.

We have reviewed the Patient Registry and Assessment form after completing the pilot study.

Then we started proper research on 1st of November 2014 and followed the process flow chart as below.

Process flow chart



Statistical Analysis of the data collected



Comparison of two chemotherapy schedules



Ascertain the better chemotherapy schedule and other recommendations



Follow up recommendations in clinical practice

Present Status

We have recruited and randomized 48 patients to the study.

Data collection completed on 38 patients. 10 patients are still undergoing treatment and continuing weekly data collection on them.

Data organization has already begun on Excel spread sheet and data entry process ~~will be~~ started in April 2015.

And we have started preliminary work for literature review and data analysis process also. We are planning to complete the study by the 31st October 2015.

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