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Safety, efficacy and survival rate comparison of Apceden® [dendritic cell (Dc) immunotherapy] with best supportive therapy in patients with refractory solid malignancies, on symptomatic treatment

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Objective: Owing to ethical considerations- a placebo control trial requires stringent necessary regulatory approvals, esp. in cancer treatment. As a result a number of trials are carried out without a placebo arm. Trials consisting immunotherapeutic products needs to be compared with a placebo to prove its efficacies of anticancer therapies in cancer patients. In order to establish the proof of concept, safety and efficacy of a dendritic cell based immunotherapy product –APCEDEN this study was carried out.

Methods: The survival data obtained for APCEDEN® therapy was compared with the survival data collected for control subjects (no active systemic treatment). The control subjects (retrospective data) was matched with the geographical region, almost similar age, same gender and ECOG performance status, stage of the disease and for the subjects whose survival data is available. The demographic matched subjects with no active systemic treatment currently and their last received supportive therapy was considered for survival analysis. The retrospective data from the subject's medical records with prior independent ethics committee's approval was collected using data capture form. The data is collected from different centers across different geographical regions in India (Hyderabad, Nasik, and Bangalore). The clinical study co-coordinators were instructed to capture the data in the predesigned data capture form. The number of patients meeting the above criteria (n=85 for retrospective control data) and n=51 subjects from APCEDEN® was compared for survival analysis. The retrospective data collected receiving no active systemic treatment is referred as control group in this paper.

Results: The survival analysis data between the treatment groups (APCEDEN® Vs control group) was analyzed twice. In survival analysis I, the total number of subjects N=51 who received the APCEDEN® was considered for analysis and in survival analysis II, about 13 subjects out of 51 subjects were excluded due to early drop outs without receiving complete therapy. In survival analysis I, the percent of censored values in the APCEDEN® treatment is 29.41% and no censored values for control group. The overall response rate in the APCEDEN® therapy is compared with the published data and fishers test results show that APCEDEN is not inferior to any of the immunotherapy product evaluated previously for solid malignant tumors. The median survival time for survival analysis I & II was found to be 173 and 211.5 days for APCEDEN treatment whereas 77 days for control group (95% CI). Hazard ratio was found to be 0.369 and 0.250 for survival analysis I & II respectively.

Conclusions: The retrospective data collected and compared with APCEDEN suggests survival benefit of more than 100 days for APCEDEN therapy. The event free survival time of APCEDEN therapy was about 439 days in patients who showed objective response at first evaluation. Safety and efficacy data of APCEDEN was found to be comparable with already published data.

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