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Arch Med 2018, Volume 10
DOI: 10.21767/1989-5216-C2-006

World Congress on
Novel Trends and Advances in Biotechnology,
Cell & Stem Cell Research &
Joint Event On
15TH Annual Congress on Pediatrics
November 28-29, 2018 Barcelona, Spain

Safety and effectiveness of nimotuzumab in the treatment of advanced head and neck cancer patients in open population

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Epidermal Growth Factor Receptor (EGFR) can be overexpressed in Head and Neck Cancer (HNC). Nimotuzumab is a humanized monoclonal antibody (hMab) that binds to the EGFR. A phase IV study was conducted in advanced head and neck newly diagnosed and recurrent cancer patients to evaluate safety and efficacy of nimotuzumab. Four therapeutic schemes were evaluated: Nimotuzumab, nimotuzumab+Chemotherapy (Nimo+CT), nimotuzumab+Radiotherapy (Nimo+RT) and nimotuzumab+Chemo+Radiotherapies (Nimo+CRT). Common toxicity criteria to evaluate Adverse Events (AEs) (version 3.0) was used to classify AEs; Kaplan-Meier curves were compared by the non-parametric Log-rank method and Cox regression was applied for subgroup analyses. A total of 225 patients were included. Most AEs were classified as grade I, AEs related to the product were reported in 36 patients. In this subgroup, most frequent events were anemia, leukopenia, neutropenia, anorexia, nausea, vomiting, asthenia and fever. In the newly diagnosed subset (n=155), although no significant difference was shown in the Intent-to-treat (ITT) analysis, there was a trend toward a benefit in favor of Nimo+CRT, not just related to Progression-Free-Survival (PFS) (22.4 months; p=0.065), but also to Overall Survival (OS) (24.3 months; p=0.089), with higher survival rates at 12 and 24 months for PFS (67.3% and 46.3%, respectively) and OS (70.1% and 50.3%, respectively), compared to the other regimens. Administration of nimotuzumab was safe in the treatment of advanced HNC patients and well tolerated despite the combination with CRT.

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