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| Protocol Title | **Hyperfractionated concurrent chemoradiation against conventional concurrent chemoradiation in locally advanced head and neck carcinoma: a prospective randomised trial** |
| Research Center Number | 1 |
| Research Center | Department of Radiotherapy, JN Medical College, Aligarh Muslim University, Aligarh, Uttar Pradesh, India |
| Indications | Patients with Locally Advanced Unresectable Head & Neck Squamous Cell Carcinoma |
| Research Purpose | This study aims to find out the efficacy and adverse reactions of conventional concurrent chemo-radiotherapy and hyperfractionated CRT in patients of advanced stages of carcinoma of head and neck in terms of. . .<br>1.Acute toxicities<br>2.Late toxicities<br>3.Response to therapy<br>. |
| Research Design | Prospective, randomized, controlled, open, phase II/III trial. |
| Case Grouping | • Study group: HF-CRT<br>• Control group:CF-CRT |

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| Inclusion Criteria | • Histologically confirmed squamous cell carcinoma of the head and neck.<br>• Unresectable, non-metastatic disease.<br>• Age >18 years<br>• Karnofsky performance status (KPS) of > 60<br>• Adequate hematologic (Hb >10 gm/dl , WBC >4000/l and platelets >100,000/microlitre), renal (serum creatinine <1.4 mg/dl) and hepatic (serum bilirubin <1 mg/dl) functions.<br>• No previous radiotherapy or chemotherapy<br>• Measurable tumor mass. |

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| Exclusion Criteria | • Patients who refuse to give a consent.<br>• Serious concomitant diseases.<br>• History of any prior or concurrent cancer in last 5 years.<br>• Patients with tumors of nasal cavity, paranasal sinuses, salivary gland and nasopharynx.<br>• Pregnancy or breast-feeding.<br>• Prior chemotherapy or radiotherapy |
| Pre-treatment Evaluation | • History and Physical examination<br>• Measurement of detectable mass by physical examination including complete ENT examination with Indirect and Direct Laryngoscopy.<br>• Chest X-Ray<br>• CT scan face and neck (contrast enhanced). Blood cell count with differential counts, liver function studies, blood urea nitrogen and serum creatinine<br>• Dental examination<br>• Orthopantogram (OPG) ,in clinical suspicion of mandibular involvement. |

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| Randomization | Patients satisfying inclusion criteria are randomized into two treatment arms-<br><br>A. Arm 1<br><br>B. Arm 2<br><br>(by computer generated random table number) |
| Intervention | • Study Group : Hyperfractionated RT (81.6Gy/68 fractions /10 fractions per week, 1.2Gy/ fraction, twice daily at 6 hours interval) with concurrent chemotherapy cisplatin 40mg/$m^2$<br><br>• Control Group: Conventional RT (70Gy/35 fractions /5 fractions per week, 2Gy/ fraction /day) with concurrent chemotherapy cisplatin 40mg/$m^2$ |
| Endpoints | Primary Endpoint:<br><br>The primary endpoint of the study was response to therapy.<br><br>Secondary Endpoint:<br><br>The secondary endpoints were acute and late treatment-induced toxicities. |

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| Statistical considerations | • The treatment-induced response was analyzed and compared in both the radiation groups. The frequency of acute and late toxicities was also compared.<br>• Data was analyzed using Pearson's chi square test and Fisher's exact test.<br>• All the tests were performed using computer program SPSS, version 16.0.<br>• A p-value of <0.05 was considered as statistically significant. |

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