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928TiP Induction versus adjuvant gemcitabine/cisplatin in locally advanced non-metastatic nasopharyngeal carcinoma: A randomised phase III trial

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Background: The standard of care for locally advanced nasopharyngeal carcinoma is radical chemoradiation (CRT). Recent advances in radiation techniques and supportive measures resulted in improvement of locoregional control and quality of life. However distant failure is still the main challenging reason of poor survival Addition of systemic therapy to concurrent CRT is widely used and accepted as an option to reduce these failures, however selection of chemotherapy regimen and timing in relation to CRT is controversial. Doublet and triplet chemotherapy regimens using cisplatin and 5FU are thoroughly investigated in this setting. In spite of significant improvement in disease free survival and overall survival they were poorly tolerated. Hence, a minority of patients in the daily practice could tolerate those studied regimens as proposed. Recently, in multicenter randomized trial, Zhang and his group

investigated gemcitabine and cisplatin as induction chemotherapy (ICT) added to CRT. It showed improvement in recurrence free survival and overall survival. More importantly 96.7% of the experimental arm completed the treatment protocol. This was further confirmed by an updated network of meta analysis by Bongiovanni et al. Again, the question of "when" is still valid. Our proposal is to compare tolerable regimen in induction versus adjuvant settings.

Trial design: This is a prospective, non-blinded, open label, randomized phase III study. The patients will be randomised to one of two arms: Arm 1: patients will receive three cycles of IC gemcitabine/cisplatin followed by radical CRT Arm 2: Patients will receive radical CRT followed by three cycles of AC gemcitabine/cisplatin Patients fulfilling the eligibility criteria will be randomized either for ICT followed by CRT or CRT followed by ACT. Chemotherapy protocols for either ICT or ACT, 3 cycles of: Cisplatin: 80 mg/m² Day 1; every 21 days cycle gemcitabine 1000 mg/ m² Day 1,Day 8; every 21 days cycle. CRT: Intensity Modulated Radiotherapy (IMRT) 70 Gy/ 35 Fractions over 7 weeks with cisplatin 100 mg/m² every 3 weeks.

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929TiP HERODOTUS: Head and neck cancers international COVID-19 collaboration: An international registry on head and neck cancer with COVID-19

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Background: Studies on patients with cancer and COVID-19 have indicated a high mortality rate compared with the general population. Patients with head and neck cancer are thought to be prone to complications following COVID-19 infection due to their older age, smoking habits, and pre-existing cardiopulmonary comorbidities, in addition to cancer therapy. Our aim is to study the effect of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection on patients with head and neck cancers.

Trial design: Head and Neck cancers international COVID-19 Collaboration (HER-ODOTUS) registry is a multicentre observational study composed of a cross-sectional component and a longitudinal cohort component. Eligibility criteria were the presence of any head and neck cancer and a COVID-19 diagnosis, either laboratory confirmed with RT-PCR, suspected with symptoms and contacts, or radiologically suspected cases with lung imaging features consistent with COVID-19 pneumonia and symptoms. Patients of any age, sex, histology, or stage were considered eligible, including those in active treatment and clinical follow-up. Clinical data will be extracted from medical records of consecutive patients from Jan 1, 2020 and will be collected until the end of the pandemic declared by WHO. Data on demographics, oncological history and comorbidities, COVID-19 diagnosis, and course of illness and clinical outcomes will be collected. Associations between demographic or clinical characteristics and outcomes will be measured with odds ratios (ORs) with 95% CIs using univariable and multivariable logistic regression, with established prognostic factors included in multivariable analysis. The registry continues to accept new sites and patient data.

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