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**TORIPALIMAB IN COMBINATION WITH CONCURRENT CHEMORADIATION IN PATIENTS WITH ADVANCED/METASTATIC ESOPHAGEAL CARCINOMA: PROTOCOL FOR A SINGLE-ARM, PROSPECTIVE, OPEN-LABEL, PHASE II CLINICAL TRIAL**

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**Background** Esophageal carcinoma is a disease with high morbidity and mortality in China and, recently, Immune checkpoint inhibitors(ICIs) combined with chemotherapy have shown good efficacy and safety for treatment; however, some patients still suffer from tumor progression or metastasis after treatment. Clinical studies have confirmed that immunotherapy combined with chemoradiotherapy can significantly improve the prognosis of patients with advanced esophageal cancer, but the efficacy and safety of adding radiotherapy to immunotherapy and chemotherapy have been less reported.

**Methods** This is an open-label, single-arm, and single-center phase II trial. Patients with unresectable stage IV esophageal squamous cell carcinoma(ESCC) who had not received prior systemic therapy were enrolled. The patients were treated with two cycles of toripalimab (240 mg d1, Q3W) combined with induction chemotherapy (paclitaxel 135–175 mg/m<sup>2</sup>, d1 +carboplatin AUC=4–6, d1, Q3W), sequentially combined with concurrent chemoradiotherapy (30–50 Gy in 15–25 fractions, paclitaxel 135–175 mg/m<sup>2</sup>, d1+carboplatin AUC=4–6 d1, Q3W), followed by maintenance treatment with toripalimab (240 mg d1, Q3W) for 1 year. The primary objective of this trial is to evaluate the progression-free survival (PFS) of this combination therapy; and the secondary objective is related to the assessment of objective response rate (ORR), the disease control rate (DCR), the duration of remission (DOR), the 1- and 2-year overall survival(OS) rates, the safety and tolerability of patients to treatment, and the identification of the changes in the health-related quality of life (HRQoL) of patients. Furthermore, we aimed to identify predictive biomarkers (such as the expression of PD-L1 ctDNA and cytokines) and to explore the relationship between these biomarkers and tumor response to the study treatment.

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**Trial Registration** ChiCTR(ChiCTR2100046715). Registered on the 27th of May 2021.

**Ethics Approval** The study protocol is approved by Ethics Committee of Sichuan Cancer Hospital (SCCHEC-02-2021-021). Changes to the protocol will be communicated via protocol amendment by the study principal investigators. Written informed consent will be obtained from all participants.

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