BERLIN 2025 ESMO congress

13190

Perioperative camrelizumab plus chemotherapy in locally advanced squamous cell carcinoma of the head and neck (CAMORAL): A multicenter, open-label, randomized, phase II Study

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Background

While neoadjuvant chemoimmunotherapy for locally advanced head and neck squamous cell carcinoma (HNSCC) has shown promising pathological remission, long-term outcomes of this strategy remain unclear. Here, we aimed to determine survival outcomes of neoadjuvant-adjuvant treatment with the programmed cell death receptor 1 (PD-1) camrelizumab and chemotherapy in HNSCC patients.

Methods

This multicenter, open-label, randomized, phase II trial enrolled patients aged 18-75 years with previously untreated, resectable stage III-IVb HNSCC. Eligible patients were randomized (1:1) to receive either two 3-week cycles of albumin-bound paclitaxel (100 mg/m^2 on Days 1, 8, 15), carboplatin (area under the curve [AUC] 5 on Day 1), and camrelizumab (200 mg on Day 1), followed by surgery, risk-adapted adjuvant radiotherapy, and up to 15 doses of camrelizumab (neoadjuvant-adjuvant group), or upfront surgery followed by risk-adapted adjuvant radiotherapy/chemoradiotherapy (control group). The primary endpoint was 2-year event-free survival (EFS). Secondary endpoints were 2-year overall survival (OS), major pathological response (MPR), pathological complete response (pCR), and safety.

Results

A total of 125 patients were randomized to neoadjuvant-adjuvant group (n=63) or control group (n=62). At the time of analysis, the median follow-up was 24.6 months. The 2-year EFS rate was 77.8% in the neoadjuvant-adjuvant group versus 46.1% in the control group (hazard ratio [HR] for progression, recurrence, or death, 0.344; 95% confidence interval [CI], 0.174-0.678; P=0.0020), and the corresponding 2-year OS was 92.0% and 69.1%, respectively (HR, 0.253; 95% CI, 0.101-0.636; P=0.0035). MPR and pCR were observed in 47.6% and 25.4% of patients in the neoadjuvant-adjuvant group, respectively. Grade ≥3 treatment-related adverse events occurred in 58.7% of patients in the neoadjuvant-adjuvant group and 21.0% in the control group.

Conclusions

Neoadjuvant camrelizumab plus chemotherapy significantly improved 2-year EFS in patients with resectable locally advanced HNSCC, without compromising treatment safety.

Clinical trial identification

ChiCTR2000037980.

Legal entity responsible for the study

The authors.

Funding

Has not received any funding.

Disclosure

All authors have declared no conflicts of interest.