Official Title of the study:Precision Treatment of Recurrent/Metastatic Salivary Gland Carcinoma Guided by Molecular Typing

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The first part (neoadjuvant and conversion study for locally advanced/recurrent and advanced oligometastatic salivary gland cancer patients), the second part (postoperative adjuvant therapy study for locally advanced salivary gland cancer based on MRD detection results), and the third part (rescue study for locally advanced/recurrent or distant metastatic salivary gland cancer patients who cannot tolerate or refuse surgery/radiotherapy and are rapidly progressing) of this research are studies with ORR as the primary endpoint. These parts of the research adopt a master protocol platform design, with the main purpose of screening out subgroups with therapeutic prospects. The study allows new drug regimens to be added, and ineffective regimens will be stopped from enrolling based on monitoring results. The trial is divided into two phases. In the first phase of each treatment group (experimental arm), a Bayesian Optimal Phase II design (BOP2) is used to assess the therapeutic potential of the treatment group. The first phase of the treatment groups with therapeutic potential will enter the second phase. In the first phase, each treatment group uses the Bayesian Optimal Phase II design (BOP2) for efficacy monitoring, with a type I error of 0.1 and a maximum enrollment of 10 cases. If the ORR does not exceed 10%, the therapy is considered ineffective; if it is not less than 40%, the therapy is considered to have experimental prospects. The overall efficacy of the entire study is 0.8136. Two interim analyses are set up. For example, if 6 patients are enrolled and PR + CR $\leqslant$ 0, the trial will be stopped; otherwise, enrollment will continue to the next interim analysis point. If 8 patients are enrolled and PR + CR $\leqslant$ 1, the trial will be stopped; otherwise, enrollment will continue to the next interim analysis point. If 10 patients are enrolled and PR + CR $\leqslant$ 2, the trial is considered a failure; otherwise, it is considered a success. The second phase is an expansion phase, and the promising treatment groups from the previous phase will be expanded in terms of the number of cases, using the Simon two-stage statistical method. It is assumed that the previous chemotherapy response rate is 30%, and the new treatment response rate is 50%. With a = 0.05 and 1 - β = 0.8, the minimum sample size required for the Simon two-stage method is 39, divided into two stages. In the first stage, 19 patients are enrolled. If there are $\geqslant$ 6 patients with CR/PR, enrollment will continue; otherwise, the study will be stopped. Eventually, 39 patients will be enrolled. If there are $\geqslant$ 16 patients with CR/PR, the trial is considered successful; otherwise, it is considered a failure.

In addition, the fourth part compares the accuracy of the in vitro 3D tumor cell culture drug sensitivity model for predicting drug efficacy with the actual clinical efficacy in salivary gland cancer, and the fifth part studies the diagnostic and prognostic value of FAPI PET/CT in salivary gland cancer. At least 30 patients will be initially enrolled to explore the following indicators: sensitivity = true positive rate = [TP/(TP + FN)] * 100%, missed diagnosis rate = false negative rate = [FN/(FN + TP)] * 100%, specificity = true negative rate = [TN/(TN + FP)] * 100%, misdiagnosis rate = false positive rate = [FP/(FP + TN)] * 100%. TP: true positive, FP: false positive, FN: false negative, TN: true negative.