Background Immune checkpoint inhibitors (ICIs) targeting the programmed cell death-1 (PD-1) has dramatically shifted the therapeutic paradigm of advanced tumor. However, a large proportion of patients do not achieve durable responses with anti-PD-1 monotherapy. Strategically combining immunotherapies with other systemic therapies to harness potential synergies is critical for maximizing their clinical activity and realizing the greatest benefits for patients with cancer. Chemotherapy drugs induce a form of tumor cell death that is immunologically active, thereby inducing an adaptive immune response specific for the tumor. Apatinib (VEGFR2 inhibitor) in combination with an anti-PD-1 has demonstrated synergistic antitumor effects. In our previous research, steady-state of apatinib (250 mg qd) plasma drug concentration was achieved by day 3. Camrelizumab and sintilimab are humanized anti-PD-1 antibody. We aim to assess time window, efficacy and safety of patients who receive anti-PD-1 antibody multimodal combination as first-line treatment of advanced solid tumor.

Methods This multicentre, open-label, exploratory cohort study. Eligible patients were aged 18–70 years, and had histologically or cytologically confirmed advanced solid tumors, an Eastern Cooperative Oncology Group performance status of 0 or 1, and received no previous anti-tumor treatment for advanced disease. 180 patients were assigned to three group: Camrelizumab/sintilimab (200 mg, iv, d1, q3w, 24 months) plus standard chemotherapy (d1-3), Camrelizumab/sintilimab (200 mg, iv, d1, q3w, 24 months) plus apatinib (250 mg, po, d1, qd), Camrelizumab/sintilimab (200 mg, iv, d1, q3w, 24 months) plus standard chemotherapy (d1-3) and apatinib (250 mg, po, d1, qd). Tumor tissue and matched blood of all patients will be collected for NGS-based 727 genes panel assay, and the blood samples will be collected until disease progression. Meanwhile, plasma drug concentrations were detected by daily measurement of trough and peak concentrations (d0, 1, 2, 3, 21, 42, 63). The primary endpoint of this study is progression free survival (PFS), and the secondary endpoints include objective response rate (ORR), disease control rate (DCR), overall survival (OS) and safety. In addition, exploratory analysis was performed to comprehensively assess the relationship between gene status and efficacy, plasma drug concentrations and biological effects. This study is registered with ClinicalTrials.gov, number NCT04282278.

Results N/A

Conclusions N/A

Trial Registration ClinicalTrials.gov, number NCT04282278.

Ethics Approval The study was approved by the Fourth Hospital of Hebei Medical University Institution’s Ethics Board, approval number 2020012.

http://dx.doi.org/10.1136/jitc-2020-SITC2020.0327