Rationale and design of a phase Ib / II trial y of capox regimen combined with sindilimab and bevacizumab as first-line treatment for recurrent or metastatic gastric and gastroesophageal junction adenocarcinoma

2022-08-31

1、 Purpose

1. 1Main purpose:

The appropriate dose of bevacizumab combined therapy was determined by stage IB;The main purpose of phase II was the objective response rate (ORR) of the experimental group.

1. 2Secondary purpose:

It included progression free survival (PFS), overall survival (OS), disease control rate (DCR), duration of remission (DOR), and adverse reactions;QOL and safety of the subjects were evaluated.And to explore the relationship between biomarkers in tumor tissues and peripheral blood biomarkers and curative effect.

2、 Research design, methods and steps

This is a multicenter, single arm, prospective, open label, randomized phase Ib / II clinical trial (Registration Number: chictr220059975).This study was funded by the 13th five year plan.In this study, we prospectively enrolled patients with unresectable recurrent or metastatic gastric and esophagogastric junction adenocarcinoma, both male and female, who received capox regimen combined

with sindilimab and bevacizumab as the first-line treatment for advanced gastric cancer.In phase IB, 3 + 3 dose climbing design was used to explore the dosage of bevacizumab in quadruple regimen.The phase II study was designed as study B. according to the bevacizumab dose determined in the phase IB study, the enrolled patients were treated with four drug combination regimen for 4-6 cycles. If PD did not occur after evaluation, capecitabine combined with sindilimab and bevacizumab maintenance treatment could be given until disease progression, intolerable toxicity, new anti-tumor treatment, withdrawal of informed consent, loss of follow-up or deathOr other investigators determine that treatment should be stopped.