

Personalized mRNA Cancer Vaccine for Gastrointestinal Solid Tumor Treatment

NCT07067385

Status	RECRUITING
Phase	Phase 1
Sponsor	Ruijin Hospital
Enrollment	40 participants

Key Eligibility Criteria

Inclusion (5)

- Voluntarily signs the informed consent form, and has good compliance.
- Male or female, aged 18 years or older.
- Patients with advanced gastrointestinal tumors: histologically and/or cytologically confirmed recurrent or metastatic gastrointestinal solid tumors not amenable to surgical or local curative treatment, with at least one measurable lesion as defined by RECIST v1.1. Eligible patients must have experienced disease progression following standard antitumor therapy or be unable or unwilling to receive standard treatment.
- Patients with resectable gastrointestinal solid tumors for adjuvant treatment: tumors must be confirmed as completely resected (R0 or R1) by postoperative histopathology, with no prior neoadjuvant therapy, and assessed as fully resectable by imaging.
- Neoantigen load requirement: at least 10 predicted neoantigen epitopes.

Exclusion (45)

- ECOG performance status of 0 or 1.
 - Life expectancy of at least 6 months.
 - Adequate organ and hematologic function, with no severe dysfunction of the heart, lungs, liver, kidneys, or immune system, based on the following laboratory values:
 - 1. Hematology: ANC $\geq 1.5 \times 10^9/L$, WBC $\geq 3 \times 10^9/L$, PLT $\geq 100 \times 10^9/L$, HGB ≥ 90 g/L. Within one week before screening, the subject must not have received blood or platelet transfusions, G-CSF, or erythropoietin (EPO);
 - 2. Renal function: Serum creatinine $\leq 1.5 \times$ ULN or creatinine clearance ≥ 50 mL/min (calculated using the Cockcroft-Gault formula);
 - 3. Liver function: AST and ALT $\leq 3 \times$ ULN ($\leq 5 \times$ ULN for patients with liver cancer or liver metastases); TBIL $\leq 1.5 \times$ ULN (patients with Gilbert's syndrome: TBIL $\leq 3 \times$ ULN);
 - 4. Coagulation: INR $\leq 2 \times$ ULN or APTT $\leq 1.5 \times$ ULN (except for patients on anticoagulants);
 - 5. Endocrine function: TSH within normal limits. Note: If baseline TSH is outside the normal range but free T3 and free T4 are within normal limits, the subject is still eligible.
 - \. Agrees to provide peripheral blood samples and, optionally, fresh peritumoral tissue for sequencing.
- ... and 40 more (see full listing online)

Locations (1 total)

Ruijin Hospital, Shanghai, SH, China

<https://clinicaltrials.gov/study/NCT07067385>

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