

Clinical Study of Personalized mRNA Vaccine Encoding Neoantigen Alone in Subjects With Advanced Digestive System Neoplasms

NCT06019702

Status	RECRUITING
Phase	Phase 1
Sponsor	Sir Run Run Shaw Hospital
Enrollment	20 participants

Key Eligibility Criteria

Inclusion (1)

- Male or female, ≥ 18 years old and ≤ 75 years old, with the ability to understand and provide signed and witnessed informed consent, and agree and are able to comply with protocol requirements.

Exclusion (24)

- Expected survival ≥ 6 months.
- Eastern Cooperative Oncology Group (ECOG) performance status score of 0 ~ 2.
- Sufficient tumor tissue samples can be obtained from subjects for genetic analysis, with at least 2 puncture tissues with a tumor purity of $\geq 50\%$ required for puncture samples and at least 0.5cm of tissue required for surgical samples. Alternatively, the original gene sequencing data required for tumor neoantigen analysis can be provided, including full exon sequencing data of tumor tissue, transcriptome sequencing data, and full exon sequencing data of peripheral blood.
- Echocardiographic evaluation: left ventricular ejection fraction (LVEF) $\geq 50\%$.
- The organ function level must meet the following requirements: absolute neutrophil count (ANC) $\geq 1.5 \times 10^9/L$, platelet count (PLT) $\geq 80 \times 10^9/L$, hemoglobin (Hb) ≥ 90 g/L; serum total bilirubin (TBIL) $\leq 1.5 \times$ ULN, aspartate aminotransferase (AST) and alanine aminotransferase (ALT) $\leq 2.5 \times$ ULN (if there is liver metastasis, TBIL $\leq 3 \times$ ULN, AST, ALT $\leq 5 \times$ ULN are allowed), serum albumin ≥ 28 g/L, serum creatinine $\leq 1.5 \times$ BUN, Glomerular filtration rate ≥ 50 mL/min, prothrombin time (PT) and activated partial thromboplastin time (APTT) and international standardized ratio (INR) $\leq 1.5 \times$ ULN (without anticoagulant therapy) .

... and 19 more (see full listing online)

Locations (1 total)

Department of General Surgery, Institute of Minimally Invasive Surgery, Sir Run Run Shaw Hospital, Hangzhou, Zhejiang, China