

Phase I Study of the Safety, Tolerability, and Efficacy of an Engineered Mitochondrial Vaccine in Advanced Solid Tumors

NCT06927297

Status	RECRUITING
Phase	Phase 1
Sponsor	West China Hospital
Enrollment	12 participants

Key Eligibility Criteria

Inclusion (13)

- Patients aged 18 to 75 years at the time of acquisition informed consent form.
- Patients with advanced malignant solid tumors such as non-small cell lung cancer or colorectal cancer, confirmed by histology or cytology, who are unable to receive or tolerate standard treatments, or who refuse standard treatments, exhibit positive expression of target antigens in the tumor tissue.
- The presence of at least one measurable or evaluable lesion according to RECIST v1.1 criteria.
- Eastern Cooperative Oncology Group (ECOG) performance status score: 0-2.
- Predicted survival time e3 months.

... and 8 more (see full listing online)

Exclusion (14)

- The patient has a history of other tumors in the past, except for the history of malignant tumors that have been cured and have not recurred within 5 years before screening, such as basal cell carcinoma of the skin, squamous cell carcinoma of the skin, superficial bladder cancer, cervical cancer in situ, and intramucosal cancer of the gastrointestinal tract, which the investigator considers to be eligible for enrollment.
- Have any uncontrolled clinical diseases (e.g., diseases of the respiratory system, circulatory system, digestive system, nervous system, hematologic system, urogenital system, endocrine system) or psychiatric or other major medical condition that the investigator considers to interfere with the provision of informed consent, to interfere with the interpretation of the trial results, to pose a risk to the study participants, or to otherwise interfere with the achievement of the study objectives.
- Have any active autoimmune disease or a history of autoimmune disease. Participants with asthma for which medical intervention with bronchodilators was required could not be included.
- Allergy to the trial drug (including any excipients). Previous history of severe allergy to any drug, food or vaccination, such as anaphylactic shock, allergic laryngeal edema, allergic dyspnea, allergic purpura, thrombocytopenic purpura, local allergic necrosis reaction (Arthus reaction), etc.
- There are contraindications to subcutaneous injection.

... and 9 more (see full listing online)

Locations (1 total)

West China Hospital, Sichuan University, Chengdu, Sichuan, China

<https://clinicaltrials.gov/study/NCT06927297>

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