

# High - Dose Vitamin C Infusion Regimen Based on Pharmacokinetic Characteristics for Patients With Advanced Malignant Solid Tumors

NCT07121036

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Status	RECRUITING
Phase	Phase 1
Sponsor	Zhongnan Hospital
Enrollment	18 participants

## Key Eligibility Criteria

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### Inclusion (5)

- 1. Aged 18 - 75 years old, regardless of gender. 2. The subject voluntarily participates, gives full informed consent, signs a written informed consent form, and has good compliance.
- 3. Histologically or cytologically pathologically diagnosed as advanced or metastatic malignant solid tumor.
- 4. Physical function status: Eastern Cooperative Oncology Group (ECOG) performance status 0 - 1.
- 5. The patient must have at least one measurable lesion (RECIST 1.1). 6. Sufficient bone marrow, liver, kidney, and heart function were recorded within 7 days before enrollment, and the patient is suitable for routine chemotherapy indicated clinically according to normal care standards.
- 7. No history of calcium oxalate kidney stones. 8. Expected survival  $\geq$  12 weeks. 9. Pathological immunohistochemistry requires a negative catalase result. 10. Patients who are undergoing systemic anti - tumor treatment and have disease progression can also enter the protocol, continue the same treatment or start a different chemotherapy regimen without interruption.

### Exclusion (10)

- 1. Lack of pathological diagnosis of malignant solid tumor. 2. The patient currently has central nervous system (CNS) metastasis or a history of brain metastasis.
- 3. Severe gastrointestinal diseases, including active bleeding. 4. Patients with severe or uncontrolled infections, heart or nervous system diseases.
- 5. Major surgery within 4 weeks or local radiotherapy within 7 days before the administration of the study drug.
- 6. Dementia or severe mental status changes that prevent obtaining informed consent.
- 7. Women of childbearing potential must use an acceptable contraceptive method during the study and must undergo a pregnancy test within 7 days after the first chemotherapy.

... and 5 more (see full listing online)

## Locations (1 total)

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Zhongnan Hospital of Wuhan University, Wuhan, Hubei, China