

# JAK Inhibitors for Solid Malignant Tumor Patients With Immune Checkpoint Inhibitors-related Dermatitis: A Open-lable, Single Arm, Phase IIa Trial

NCT06715982

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<b>Status</b>	RECRUITING
<b>Phase</b>	Phase 2
<b>Sponsor</b>	Shixiu Wu
<b>Enrollment</b>	35 participants

## Key Eligibility Criteria

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### Inclusion (7)

- Eligible patients must be at least 18 years of age with a confirmed diagnosis of a solid malignant tumor.
- Patients who have received treatment with any Food and Drug Administration (FDA)-approved monoclonal antibodies targeting CTLA-4, PD-1, or PD-L1, either as monotherapy or in combination.
- Patients who are diagnosed with Immune checkpoint inhibitors (ICI)-related dermatitis graded as 3-4 according to Common Terminology Criteria for Adverse Events Version 5.0.
- Patients with ICI-related dermatitis who were either treatment-naïve (having received no prior steroids or immunosuppressants) or were refractory to previous treatment with corticosteroids and/or immunosuppressive agents.
- Adequate bone marrow and organ function, as outlined below, must be confirmed:  
... and 2 more (see full listing online)

### Exclusion (5)

- Patients with dermatological diseases (e.g., chronic inflammatory skin disorders such as atopic dermatitis or psoriasis) that, in the investigator's assessment, may elevate the risks associated with study participation or compromise the interpretation of study outcomes.
- Patients who currently present with persistent dermatitis (grade  $\geq 1$ , according to CTCAE v5.0) attributable to therapeutic interventions other than ICIs treatment.
- Female who is pregnant, breastfeeding, or considering pregnancy during the study.
- Current or past history of infection including herpes zoster or herpes simplex, human immunodeficiency virus (HIV), active Tuberculosis, active or chronic recurring infection, active hepatitis B or C.
- Any other medical, psychiatric, or logistical condition that, in the judgment of the investigator, could pose a safety risk, affect protocol compliance, or interfere with the conduct or interpretability of the study.

## Locations (1 total)

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Quzhou people's hospital, Quzhou, Zhejiang, China

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<https://clinicaltrials.gov/study/NCT06715982>

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