

# Study to Assess the Safety and Efficacy of ZX-7101A for Oral Suspension in Chinese Pediatric Participants 2 to 11 Years of Age With Influenza

NCT07095257

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Status	RECRUITING
Phase	Phase 3
Sponsor	Nanjing Zenshine Pharmaceuticals
Enrollment	168 participants

## Key Eligibility Criteria

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### Inclusion (9)

- $\geq 2$  years of age at the time of randomization, males or females.
  - Patients in the screening period met the following criteria:
  - Rapid influenza diagnostic test (RIDT) or polymerase chain reaction (PCR) test positive;
  - Axillary temperature  $\geq 37.5$  at screening; If taking antipyretics, axillary temperature  $\geq 37.5$  after taking the drug (more than 4 hours).
  - At least one of the influenza-related respiratory symptoms is moderate or greater in severity: nasal congestion/runny nose and coughing.
- ... and 4 more (see full listing online)

### Exclusion (22)

- Patients with severe or critically influenza virus infection (Meet any one of the following criteria).
  - Severe cases with any of the following conditions: Dyspnea and/or increased respiratory rate: more than 30 breaths per minute for children over 5 years old; over 40 times per minute for children aged 2 to 5.
  - Changes in consciousness: slow response, drowsiness, restlessness, convulsions, etc.
  - Severe vomiting or diarrhea, with signs of dehydration. oliguria: Children with urine output  $< 0.8$  mL/(kg · h), or infants with daily urine output  $< 200$  mL/m<sup>2</sup>, preschool children  $< 300$  mL/m<sup>2</sup>, school aged children  $< 400$  mL/m<sup>2</sup>, or experiencing renal failure;
  - Critical cases with any of the following conditions (Including but not limited to) Respiratory failure; Acute necrotizing encephalomyopathy; Shock septic; Multiple organ dysfunction; Other serious clinical situations require intensive care Note: Refer to the Expert Consensus on Diagnosis and Treatment of Childhood Influenza (2020 Edition)
- ... and 17 more (see full listing online)

## Locations (2 total)

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West China Second University Hospital, Sichuan University, Chengdu, Sichuan, China  
Children's Hospital Zhejiang University School of Medicine, Hangzhou, Zhejiang, China