

# A Small Sample Prospective Clinical Study of Azvudine Tablets to Promote Clinical Cure in Patients With Chronic Hepatitis B

NCT07307586

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Status	RECRUITING
Phase	Phase 3
Sponsor	Zhigang Ren
Enrollment	120 participants

## Key Eligibility Criteria

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### Inclusion (5)

- All subjects must meet the following criteria to be eligible for inclusion in the trial:
- Meet the diagnostic criteria for viral hepatitis as outlined in the Chinese Medical Association's Hepatology Branch Guidelines for the Prevention and Treatment of Chronic Hepatitis B, with patients demonstrating sustained positivity for hepatitis B e antigen (HBeAg) and hepatitis B surface antigen (HBsAg) for at least six months;
- HBV DNA load  $> 20,000$  copies/mL and HBsAg  $< 1,500$  IU/mL;
- Serum alanine aminotransferase (ALT)  $> 2$  times the upper limit of normal;
- No prior antiviral therapy prior to hospital admission.

### Exclusion (10)

- All subjects meeting any of the following criteria shall be excluded from this study:
- Individuals co-infected with other hepatotropic viruses, such as hepatitis A, C, D, or E viruses, or HIV;
- Patients with concomitant liver metabolic disorders, cirrhosis, autoimmune-related diseases, or other chronic conditions;
- Pregnant or breastfeeding women, or those planning pregnancy within one year;
- Patients who have received or are currently undergoing antineoplastic therapy;
- ... and 5 more (see full listing online)

## Locations (1 total)

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The First Affiliated Hospital of Zhengzhou University, Zhengzhou, Henan, China