A Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Antiviral Activity of BJT-778 in Subjects with Chronic HBV Infection (CHB) and Chronic HDV Infection (CHD).

ACTRN12623000105640

Status	RECRUITING
Phase	Phase 2
Sponsor	Bluejay Therapeutics Inc.
Enrollment	72 participants

Plain Language Summary

Hepatitis B and Hepatitis D are serious liver infections affecting hundreds of millions of people worldwide. Hepatitis D can only infect people who already have hepatitis B, and when both are present together, the liver disease progresses much faster, leading to cirrhosis, liver failure, or liver cancer. Current treatments are limited. This study is testing a new monoclonal antibody — a laboratory-made protein designed to neutralise the viruses and clear them from the body — called BJT-778.

The trial is assessing the safety, tolerability, and antiviral activity of BJT-778, looking at how well it reduces virus levels in the blood and how the body responds to it. Participants will receive injections of the study drug over a defined period and will be monitored closely with blood tests and clinical assessments.

You may be eligible if you are aged 18 to 70, have been chronically infected with hepatitis B for at least 6 months, also have hepatitis D, are currently on antiviral medication, and have adequate organ function. People with cirrhosis, liver failure, other liver diseases, or prior organ transplants are not eligible.

Key Eligibility Criteria

Inclusion (11)

- ••Able and willing to provide written informed consent (signed and dated) and any authorizations required by local law and can comply with all study requirements
- ••Male or female adults between 18 and 70 years of age
- ••BMI 18-40 kg/m2
- ••Chronic HBV infection greater than or equal to 6 months (e.g., positive for serum HBsAg greater than or equal to 6 months)
- ••Plasma HBV DNA less than 100 IU/ml at Screening

... and 6 more (see full listing online)

Exclusion (15)

- ••Evidence of cirrhosis
- ••History of decompensated liver disease as evidenced by ascites, hepatic encephalopathy, and/or gastric or esophageal varices
- ••History of liver disease other than Hepatitis B (i.e., NASH, alcohol associated hepatitis, cholestatic liver disease, etc.)
- ••Chronic hepatitis C virus (HCV) infection; subjects with past HCV RNA infection that was successfully treated must be HCV RNA negative and at least 24 weeks post treatment.
- ••Received solid organ or bone marrow transplant

... and 10 more (see full listing online)

Locations (9 total)

Royal Prince Alfred Hospital - Camperdown, NSW,VIC, Australia

The Alfred - Melbourne, NSW,VIC, Australia

St Vincent's Hospital (Melbourne) Ltd - Fitzroy, NSW,VIC, Australia

... and 6 more locations