

# A study of the safety of combining BIT225 with pegylated interferon and ribavirin, in patients with hepatitis C virus infection, including measurement of the concentration and distribution of BIT225 in the body and antiviral activity.

ACTRN12612000828820

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Status	COMPLETED
Phase	Phase 2
Sponsor	Biotron Limited
Enrollment	24 participants

## Key Eligibility Criteria

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### Inclusion (13)

- Males or females, aged 18 to 55 years
  - Chronic hepatitis C infection (defined as persistent HCV infection as diagnosed by detection of HCV RNA in the blood at least 6 months from initial detection).
  - Serologic evidence of HCV infection by anti-HCV antibody test.
  - Documentation of HCV genotype 1-infection at any time prior to entry. A laboratory report must be used for documentation. Those without known genotype at screening will have a screening genotype performed.
  - HCV RNA of  $\geq 105$  IU/mL as measured by the ROCHE COBAS Amplicor Monitor 'registered trademark' version 2.0 method within 60 days of Entry
- ... and 8 more (see full listing online)

### Exclusion (37)

- Patients who have received an investigational drug for HCV.
  - Positive results for Hepatitis B (Hepatitis B surface antigen) and HIV antibody at Screening.
  - History or presence of other evidence of a medical condition associated with chronic liver disease (e.g., chronic or acute hepatitis B, acute hepatitis A, hemochromatosis, autoimmune hepatitis, Wilson's disease, Gilbert's syndrome, homozygote alpha1-antitrypsin deficiency, alcoholic liver disease, and toxin exposures).
  - Bridging cirrhosis or cirrhosis confirmed on a biopsy obtained within the past 36 months as judged by a local pathologist. Note: patients with Metavir (or equivalent index) stage 3 fibrosis on a previous biopsy or patients with no previous biopsy will require an abdominal ultrasound within 6 months of first dose showing no evidence of cirrhosis
  - History or signs of decompensated liver disease manifested by presence of Child-Pugh class B or C, ascites, variceal bleeding, or hepatic encephalopathy, spontaneous bacterial peritonitis, or other clinical signs of portal hypertension or hepatic insufficiency
- ... and 32 more (see full listing online)

## Locations (1 total)

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Thailand