

A study of the safety of BIT225 in combination with pegylated interferon and ribavirin in patients with hepatitis C virus and human immunodeficiency virus co-infection, who are naive to treatment with pegylated interferon and ribavirin, and whose HIV is currently well controlled by standard antiretroviral therapy.

ACTRN12612001189819

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| Status | COMPLETED |
| Phase | Phase 2 |
| Sponsor | Biotron Limited |
| Enrollment | 12 participants |

Key Eligibility Criteria

Inclusion (22)

- Males or females, aged 18 to 65 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, 2, or 3 at any time prior to entry. (Enrolment will be limited to 4 patients with genotype 1 and 8 patients with genotype 2 or 3).
- HCV RNA of $\geq 100,000$ IU/mL within 60 days of Entry.

... and 17 more (see full listing online)

Exclusion (38)

- Patients who have received an investigational drug for HCV or HIV, HIV vaccine, immunomodulators (e.g. interleukins, interferons, cyclosporine), systemic cytotoxic chemotherapy, or other investigational therapy within 30 days prior to Day 0.
- Positive results for Hepatitis B (Hepatitis B surface antigen or HBV DNA in subjects with isolated HBcAb, defined as negative HBsAg, negative HBsAb and positive HBcAb (acute or chronic hepatitis B)) at Screening.
- Currently have any active AIDS defining illness (according to the CDC Surveillance Case Definition for HIV infection, AIDS-Defining Conditions, updated December 5, 2008).
- 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 liver biopsy obtained within the past 36 months as judged by a local pathologist.

... and 33 more (see full listing online)

Locations (1 total)

Bangkok, Thailand