# A study of the safety of 3 months treatment with BIT225, in combination with pegylated interferon and ribavirin, in patients with chronic hepatitis C infection, compared to pegylated interferon and ribavirin alone, including measurement of the concentration of BIT225 in the blood and antiviral activity.

ACTRN12613001296729

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| **Status** | COMPLETED |
| **Phase** | Phase 2 |
| **Sponsor** | Biotron Limited |
| **Enrollment** | 60 participants |

## Key Eligibility Criteria

### Inclusion (11)

- Males or females aged 18 to 65 years.
- Chronic hepatitis C infection (HCV RNA in the blood at least 6 months from initial detection).
- Positive anti-HCV antibody test.
- HCV genotype 1 or 3
- HCV RNA of >/= 10^5 IU/mL within 60 days of Entry.

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

### Exclusion (37)

- Received an investigational drug, immunomodulator, systemic cytotoxic chemotherapy, or other investigational therapy within 30 days prior to  Day 1.
- Positive results for Hepatitis B and/or HIV antibody at Screening.
- History or presence of other evidence of a medical condition associated with chronic liver disease.
- Bridging cirrhosis or cirrhosis confirmed on a liver biopsy, or ultrasound and fibroscan, obtained within the past 36 months as judged by a local pathologist.
- History or signs of decompensated liver disease.

... and 32 more (see full listing online)

## Locations (1 total)

Thailand