A phase Ib study of oglufanide disodium (IM862) in patients with chronic HCV infection

ACTRN12606000505505

Status	TERMINATED
Phase	Phase 1
Sponsor	Implicit Bioscience Pty Ltd
Enrollment	32 participants

Key Eligibility Criteria

Inclusion (1)

• Serological evidence of hepatitis C infection by anti-HCV antibody test and HCV RNA detectable by PCR; Liver biopsy showing Metavir fibrosis stage = or <2 within 3 or 5 years, for moderate or mild disease respectively; Able to give written informed consent and comply with protocol requirements; Has failed to respond to conventional antiviral therapy, has relapsed, or has declined to receive these drugs (previous ribavirin treatment must be >6 months prior to enrolment).

Exclusion (1)

• Women who are pregnant, breastfeeding or of child-bearing potential who are not using at least two forms of acceptable methods of birth control; Co-infection with HBV or HIV; Patients who are expected to need systemic antiviral therapy at any time during their participation; Renal impairment (creatinine >0.15 mmol/L; Specific enzymes > 5x upper limit of normal, bilirubin> 30umol/L; Haematological abnormalities (Hb <110g/L, lymphocyte count <0.8x10^9/L, platelet count <100x10^9/L); History or evidence of bleeding from oesphageal varices or other conditions consistent with decompensated liver disease; History or evidence of chronic pulmonary disease associated with functional limitations; History of major organ transplantation with an existing functional graft; Haemophilia or any other condition that would preclude liver biopsy; Alcohol intake >30g/day for men or >20g/day for women or evidence of alcohol abuse within 6 months of screening; Poorly controlled diabetes mellitus; Patients taking herbal or antioxidant therapies; Substance abuse with IV or inhaled drugs; Evidence of liver disease due to other disorders (eg. untreated haemochromatosis, alcoholic liver disease, Wilson's disease, autoimmune hepatitis, toxin exposure, alpha1-antitrypsin); Persons currently (or within 3 months prior to enrolment) taking systemic immunosuppressive or immunomodulative medication including interferon (use of topical or inhalant corticosteroids is acceptable); Evidence of ongoing autoimmune disease (clinically manifest vasculitis, ANA titre >640, AMA titre >160, anti smooth muscle antibody titre >160); Acute illness within 72 hours prior to first drug administration; Administration of any investigational drug or vaccine or any registered vaccine within 30 days prior to and during the dosing phase in this study or within 5 half lives of the investigational drug, which ever is shorter; Any medical or social condition that in the opinion of the investigator would interfere with the interpretation or evaluation of the study product; Subjects in whom it is not possible to obtain a pre-dose blood sample without undue trauma or distress; Evidence of an active or suspected cancer or a history of malignancy where the risk of recurrence is >20% within 2 years; Body mass index >36 or <18; Donation or loss of more than 400ml of blood within 2 months prior to anticipated dose administration; History of clinically significant drug allergy; History of a severe seizure disorder or current anticonvulsant use.

Locations (1 total)

Australia