

HEPATITIS

New drug regimen for HCV infection

Patients infected with HCV who also have cirrhosis or HIV co-infection are often difficult to treat with established therapies. Now, the results of two phase II clinical trials published in *The Lancet* reveal that daily oral grazoprevir plus elbasvir with or without ribavirin is an effective treatment for infection with HCV genotype 1 in both of these patient groups, and in patients who are resistant to first-line therapies.

In separate trials conducted as part of the C-WORTHY study, treatment responses of patients with HCV mono-infection were compared with those with HIV and HCV co-infection, and patients with previously untreated infection with HCV with cirrhosis were compared with those with a previous null response to treatment, with or without cirrhosis.

The primary efficacy objective of both trials was a sustained virologic response (SVR; defined as an HCV RNA concentration <25 IU/ml). After 12 weeks of treatment and 12 weeks of follow-up, this objective was achieved by approximately 90% of patients with

HCV mono-infection, and HCV–HIV co-infection. HCV-infected patients with cirrhosis and those who previously did not respond to treatment (with or without cirrhosis) had similarly high rates of SVR after 12 or 18 weeks of treatment.

No participant deaths, or discontinuations of treatment were caused by adverse effects; however, minor adverse effects, including fatigue, headaches, nausea, diarrhoea or asthenia were reported by >10% of trial participants in one, or both trials.

This safety profile is of particular importance given that current approved regimens of sofosbuvir (or simeprevir), PEG-IFN and ribavirin are not well tolerated by patients with cirrhosis. Confirmation of these findings in phase III clinical trials is eagerly anticipated.

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Original articles Lawitz, E. *et al. Lancet* doi:10.1016/S0140-6736(14)61795-5 | Sulkowski, M. *et al. Lancet* doi:10.1016/S0140-6736(14)61793-1