Phase 2 data show treatment efficacy in 'difficult-to-cure' hepatitis C patients

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A Hepatitis C (HCV) drug currently under investigation, ABT-493 and ABT-530, which is an all-oral once-daily antiviral treatment, helped HCV genotype 3 patients with heavily scarred livers and no previous treatment history to achieve a 100% sustained virologic response after receiving the treatment for 12 weeks (SVR12).

Additional data from this study, also presented at The International Liver Congress today in Barcelona, Spain, show that 97% of patients with the same HCV genotype, but without scarred livers, achieved SVR12 after eight weeks on the same treatment without ribavirin (RBV).

As treatments for HCV have evolved, genotype 3 patients have become the most difficult subgroup of patients to cure.1 Although there have been recent advances in direct-acting antiviral therapies for HCV genotype 1, genotype 3 remains a challenge and is a highly prevalent strain of the infection globally, with a particularly high concentration of cases in Asia.1

The current standard of care for HCV genotype 3 is the nucleotide polymerase inhibitor sofosbuvir with weight-based RBV for 24 weeks. This recommendation comes from the Valence study where high SVR rates were seen in those who had no previous HCV treatment history, without or with scarring of the liver, known as cirrhosis (93% and 92%, respectively). However, treatment-experienced genotype 3 cirrhotic patients experienced a lower SVR rate of 60%.2

"We are pleased to see the efficacy of this two direct-acting antiviral investigational, pan-genotypic regimen has been validated for treatment-naïve Hepatitis C genotype 3 patients - with 100% of cirrhotic patients treated for 12 weeks and 97% of non-cirrhotic patients treated for eight weeks achieving sustained virologic response at 12 weeks post treatment," said Dr Paul Kwo from Indiana University School of Medicine, Indianapolis, US and one of the lead study authors. "Clinical trials are ongoing to evaluate the safety and efficacy of the investigational treatment, and we are now focusing on a larger cohort of HCV genotype 3 patients, including treatment-experienced patients."

In the international Phase 2 clinical trial, two study arms enrolled 24 cirrhotic patients each, none who had previously been treated for HCV infection. In the two patient groups taking the investigational combination treatment ABT-493 and ABT-530 with and without once-daily RBV, all achieved SVR12 after 12 weeks on treatment. No patient discontinued the study or experienced virologic failure.

In another trial treatment arm that focused on non-cirrhotic patients, 29 genotype 3-infected patients were enrolled. SVR12 was achieved by 97% (28/29) of patients with no patient experiencing virologic failure. The most common side effects were the same across both studies, including headache, and fatigue.

"These data mark another step forward in continued research efforts to address the unmet medical need among HCV patients," said Professor Frank Tacke, EASL Governing Board member. "We will be watching with close interest to see whether similar efficacy levels can be achieved for treatment-experienced genotype 3 HCV patients - a group known for being hard to cure."

More information: References:

1 US National Library of MedicineNational Institutes of Health. Review article: HCV genotype 3 - the new treatment challenge. Available from: www.ncbi.nlm.nih.gov/pubmed/24612116. Last accessed: March 2016.
2 The Hepatitis C Trust. Genotype 3: One of the Remaining Challenges for Hepatitis C. Available from: www.hepctrust.org.uk/news/may- … allenges-hepatitis-c. Last accessed: March 2016.

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