Zepatier Plus Sovaldi Works Well for Cirrhotic People With Genotype 3 of Hep C

In a recent trial, 12 weeks of the drug combination worked well regardless of whether individuals had drug-resistant virus.

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Twelve weeks of Merck's Zepatier (grazoprevir/elbasvir) plus Gilead Sciences' Sovaldi (sofosbuvir) cures hepatitis C virus (HCV) at a very high rate among those with cirrhosis and genotype 3 of the virus. This holds true regardless of any mutations their virus may have that are associated with resistance to treatment.

Publishing their findings in the journal Hepatology, researchers from the randomized open-label Phase II C-ISLE study gave 12 or 16 weeks of Sovaldi plus Zepatier, with or without ribavirin, to a group of people with genotype 3 of hep C and compensated cirrhosis (the milder form of the advanced liver disease).

The participants who had not been treated for hep C before were randomized to receive Zepatier plus Sovaldi for eight weeks (23 participants) or 12 weeks (24 participants). The participants who had been treated before (with interferon and ribavirin) were randomized to receive 12 weeks of Zepatier plus Sovaldi with ribavirin (18 participants) or without ribavirin (17 participants) or to receive 16 weeks of just Zepatier plus Sovaldi.

Ninety-one percent (21 of 23) of the first-timers to treatment who were treated for eight weeks and 96 percent (23 of 24) of the first-timers treated for 12 weeks achieved a sustained virologic response 12 weeks after completing therapy (SVR12, considered a cure).

Among those who had been treated for hep C previously in the 12 week arm, 94 percent (17 of 18) of those who received ribavirin and 100 percent (17 of 17) of those who did not were cured. Ninety-four percent (17 or 18) of those treated for 16 weeks were cured.

Overall, five participants failed to achieve an SVR12, including two who experienced viral relapse in the eight-week arm; one, in the 16-week arm, who discontinued treatment because of vomiting and cellulitis (a bacterial infection of the inner layers of the skin); and two who withdrew consent for the study or were lost to follow-up.

The likelihood of a cure was not affected by any viral mutations participants had that are associated with resistance to particular hep C drug classes.

Five participants reported serious adverse health events, including pneumonia, chest pain, opiate overdose, cellulitis and decreased creatinine (a possible indication of liver disease).

The study authors concluded that treating with this regimen for longer than 12 weeks was not necessary in this population. The study data, they stated, support the use of Zepatier plus Sovaldi for 12 weeks without ribavirin among those with genotype 3 of hep C and cirrhosis who are being treated for hep C for the first time or who have been treated before with interferon and ribavirin.

To read the Healio article, click here.

To read the study abstract, click here.

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