Eight Weeks of Mavyret Cures Hep C at High Rate in Those With Cirrhosis

This is the first major study to assess an eight-week regimen in people with all genotypes of hep C and compensated cirrhosis.

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Among people with compensated cirrhosis (the milder form of the severe liver disease), eight weeks of treatment with Mavyret (glecaprevir/pibrentasvir) cures hepatitis C virus (HCV) at a high rate.

Robert S. Brown Jr., MD, MPH, the director of the Center for Liver Disease and Transplantation at Weill Cornell Medicine in New York City, led the research team behind the single-arm, multicenter, Phase IIIb EXPEDITION-8 trial. The 390 participants, who were all being treated for the virus for the first time, included 270 people with genotypes 1, 2 4, 5 and 6 and 60 people with genotype 3. All had compensated cirrhosis.

Findings were presented in the Journal Hepatology and The Liver Meeting (the Annual Meeting of the American Association for the Study of Liver Diseases) in Boston.

The study was the first to assess an eight-week regimen in people with compensated cirrhosis and all HCV genotypes.

At the time of the study, Mavyret was approved as an eight-week regimen for those starting HCV treatment for the first time who do not have cirrhosis and as a 12-week regimen for those being treated for the first time who have compensated cirrhosis.

The study excluded those coinfected with hepatitis B virus (HBV) or HIV or who had received an organ transplant.

A total of 343 people received at least one dose of Mavyret, of whom 63% were male and 83% were white. Sixty-seven percent had genotype 1 of HCV and 18% had genotype 3.

A total of 97.7% (335 of 343) of the participants achieved a sustained virologic response 12 weeks after completing therapy (SVR12, considered a cure). Excluding the eight people about whom cure status data were missing and two others who did not complete treatment, this left a group of 335; of that group, 99.7% (334 of 335) were cured.

One participant (0.3% of the study population), who had genotype 3a of HCV, experienced a viral relapse four weeks after completing treatment.

The most common adverse health events experienced by at least 5% of the participants were fatigue (9%), itching (8%), headache (8%) and nausea (6%). Two percent of the participants experienced serious adverse health events, although none of these events led to a discontinuation of treatment. There were infrequent abnormalities in lab test results.

The study's findings about Mavyret, the authors concluded, may encourage nonspecialist health care providers to treat people with HCV and compensated cirrhosis.

Because of the study's findings, eight weeks of Mavyret was approved to treat all genotypes of HCV among those with compensated cirrhosis starting treatment for the virus for the first time.

To read the study abstract, click here.
