Faldaprevir and Deleobuvir Fare Well Against Hep C

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A trial of an interferon-free regimen of Boehringer Ingelheim's faldaprevir and deleobuvir, plus ribavirin, cured genotype 1 of hepatitis C virus (HCV) in 52 to 69 percent of study participants, MedPage Today reports. Efficacy dropped dramatically, however, when the regimen omitted ribavirin. Publishing their findings in the New England Journal of Medicine, researchers gave the protease inhibitor faldaprevir and the non-nucleoside polymerase inhibitor deleobuvir to 362 people with genotype 1 of the virus in a Phase IIb, randomized, open-label trial titled SOUND-C2.

The study participants were randomly divided into five groups:

Three groups took 120 milligrams of faldaprevir each day, plus 600 mg of deleobuvir three times a day, plus ribavirin. Eighty-one participants stayed on the regimen for 16 weeks, 80 for 28 weeks, and 77 for 40 weeks. Another 46 participants took the same regimen, but without ribavirin, for 28 weeks.

In addition, 78 participants took 120 mg of faldaprevir each day, plus 600 mg of deleobuvir twice a day (instead of three times), plus ribavirin for 28 weeks.

The study's goal was to see what percentage had a sustained virologic response 12 weeks after completing therapy (SVR12, considered a cure). Fifty-nine percent of both those in the 16-week group and those in the 28-week group who took the same regimen achieved SVR12. Fifty-two percent of those in the 40-week group achieved SVR12, as did 69 percent of those who took deleobuvir twice a day for 28 weeks. Only 39 percent of the ribavirin-free group were cured.

Ninety-four percent of the study participants reported at least one adverse side effect of the therapy. Thirty-four people (9.4 percent) experienced a serious side effect, and 27 (7.5 percent) had a life-threatening one. The most common adverse effects were rash, sensitivity to light, nausea, vomiting and diarrhea.

To read the study abstract, click here.

To read the MedPage Today report, click here.

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