Zepatier Is Safe and Effective for Women on Oral Contraceptives or HRT

A recent analysis of data from a roster of clinical trials yielded reassuring findings for this group of women who have hepatitis C.

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Women with genotypes 1 or 4 of hepatitis C virus (HCV) who are taking oral contraceptives or hormone replacement therapy (HRT) can safely and effectively treat the virus with 12 weeks of Zepatier (grazoprevir/elbasvir).

Researchers conducted a retrospective, post hoc integrated analysis of data from 12 Phase II or III clinical trials of Zepatier. They looked at data on 1,022 female participants with genotype 1 or 4 of hep C, including those who had and had not been treated before. The study cohort included some women with compensated cirrhosis (the milder form of the advanced liver disease) and HIV coinfection. The analysis excluded women with decompensated cirrhosis (the more severe form of the advanced liver disease) or evidence of hepatocellular carcinoma (HCC, the most common form of liver cancer).

Findings were presented in a poster presentation at the 52nd International Liver Congress in Paris.

All the women were treated with 12 weeks of Zepatier.

Eighty-one of the women were receiving oral contraceptive pills (OCP) or hormone replacement therapy (HRT); the remainder were not. A total of 95.1 percent of those on OCP or HRT achieved a sustained virologic response 12 weeks after completing therapy (SVR12, considered a cure) compared with 96.3 percent of those not on OCP or HRT. When the researchers excluded from their analysis those women who did not experience virologic failure after treatment, 97.5 percent of both groups were cured.

Cure rates were uniformly high across the study population’s subgroups, including those older or younger than 35, those with genotypes 1a, 1b or 4, those with an initial viral load over or below 800,000, those with or without HIV, those who had or had not been treated before and those with or without cirrhosis.

The rates of adverse health events, serious adverse health events and abnormal lab test results were similar between those who did and did not take OCP or HRT. Consequently, the researchers

concluded that Zepatier could be administered safely with OCP or HRT.

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