Merck’s Hep C Therapy Cures 99% of Those with Kidney Disease

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Twelve weeks of Merck’s grazoprevir and elbasvir cured hepatitis C virus (HCV) in 99 percent of people with genotype 1 of the virus and advanced chronic kidney disease. The C-SURFER Phase II/III clinical trial included 116 cirrhotic and non-cirrhotic participants who had stages 4 or 5 of chronic kidney disease and were either treatment naive or had failed a previous interferon-based therapy. Results were presented at the 50th International Liver Congress in Vienna, Austria.

The participants were randomized into two groups. The first was called the immediate treatment group, in which 111 people received 12 weeks of the NS3/4A protease inhibitor grazoprevir plus either the NS5A replication complex inhibitor elbasvir, taking both drugs once daily. This group did not know if it was receiving the active drugs or a placebo. The second group, called the deferred group, included 113 people who spent 12 weeks on a placebo (not knowing if it might be the actual active drugs), followed by a four-week follow-up period; then they started 12 weeks of once-daily grazoprevir and open-label elbasvir. Another 11 participants received grazoprevir and elbasvir on an open-label basis, once daily for 12 weeks. The investigators took numerous samples from this group to determine how the drugs were being processed in their bodies.

A total of 122 participants in the immediate treatment group, plus the group with 11 participants, received at least one dose of grazoprevir and elbasvir. Six of them were not included in the final analysis, because of missing data as a result of death or stopping the drugs early for reasons not related to the medications. A total of 115 or 99 percent of the 116 participants included in the final analysis were cured.

No one in the immediate treatment group stopped treatment because of adverse side effects. Five people in the deferred group, or 4 percent, dropped out of the trial because of side effects. Fourteen percent (16 of 111) of those in the immediate treatment group and 17 percent (19 of 113) of those in the deferred treatment group experienced serious adverse side effects. The most common treatment-related side effects in the immediate and deferred arms, respectively, were headache (17 percent, 17 percent), nausea (15 percent, 16 percent) and fatigue (10 percent, 15 percent).

Four people died during the initial treatment phase and the first 14 days of follow-up. One person in the deferred treatment arm died of a heart attack not related to the study medication, and three people in the deferred group died from aortic aneurysm, pneumonia and an unknown cause.

All of these deaths were judged unrelated to the hep C treatment. (The population as a whole was relatively unhealthy, so the deaths are not necessarily a surprise.)

To read the Merck press release on the study, click here.

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http://beta.docker.hepmag.com/article/grazoprevir-elbasvir-kidney-27109-333075126