



Harvoni Appears Safe and Well-Tolerated in Those With Severe Kidney Woes

The hepatitis C regimen was tested in a small group with severe kidney impairment.

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Among a small group of people with hepatitis C virus (HCV) and severe kidney impairment, Harvoni (ledipasvir/sofosbuvir) proved safe and well-tolerated in a recent trial.

Presenting their findings at the Annual Meeting of the American Association for the Study of Liver Diseases (AASLD) in Washington, DC, researchers conducted an open-label, Phase II study of 12 weeks of Harvoni among 18 people with genotype 1 of HCV and severe kidney impairment (defined as a maximum creatinine clearance of milliliters per minute).

Fourteen (78 percent) of the participants had not been treated for hep C before and two (11 percent) had cirrhosis.

All of the participants achieved a sustained virologic response 12 weeks (SVR, considered a cure) after completing therapy.

Safety-related health events occurred at a rate consistent with what would be expected given the population in the study. The most common adverse events, occurring in more than 15 percent of participants, were fatigue (22 percent), headache (22 percent) and high potassium (17 percent). Four participants (22 percent) experienced serious adverse health events, none of which were judged related to Harvoni.

None of the participants died and none stopped treatment early.

To read the conference abstract, [click here](#).

To read a press release about the study, [click here](#).
