Harvoni Is Safe and Effective for Treating Hep C in 3- to 5-Year-Olds

Ninety-seven percent of the children were cured of hepatitis C.

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Harvoni (ledipasvir/sofosbuvir) proved safe, well tolerated and highly effective against hepatitis C virus (HCV) in a small study of children who contracted the virus from their mothers and who were at least three years old but younger than six years old.

Kathleen B. Schwartz, MD, of the department of pediatrics at Johns Hopkins University School of Medicine led a research team that conducted a multicenter, open-label Phase II study of 12 weeks of Harvoni among 34 children with hep C in that age range. They published their findings in the journal Hepatology.

The participants were treated with weight-based doses of Harvoni in granular form, to be sprinkled over food or ingested orally and washed down with water. They received 33.75 milligrams of ledipasvir and 150 mg of sofosbuvir if they weighed less than 37.5 pounds or a respective 45 mg and 200 mg of the drugs if they weighed 37.5 pounds or more.

The Food and Drug Administration approved these lower-dose Harvoni formulations for children ages 3 to 12 in September.

Fourteen of the children received extra testing to assess their metabolism of Harvoni on the 10th day of their treatment. This testing indicated that the study used appropriate doses of the regimen's components.

The children had a median age of five years old. Seventy-nine percent of them were white, and 71% weighed less than 37.5 pounds. Thirty-three of the children had genotype 1 of hep C and one had genotype 4. None had cirrhosis. All contracted the virus from their mothers during gestation or delivery.

Ninety-seven percent (33 of 34) of the children achieved a sustained virologic response 12 weeks after completing therapy (SVR12, considered a cure). The one child who was not cured stopped treatment after five days because of an "abnormal drug taste."

Seventy-four percent of the children experienced at least one adverse health event, most

commonly vomiting (24% of the children), cough (21%) and fever (21%). None experienced a serious or severe (Grade 3 or 4) adverse health event.

Adverse health events that the investigators considered related to Harvoni and that occurred in more than one child included abnormal drug taste (9% of the children), fatigue (6%), vomiting (6%), insomnia (6%) and upper abdominal pain (6%). All these health events were mild, with the exception of the child experiencing the bad tast. All of the events resolved after treatment was completed.

The study is limited by the fact that none of the participants had cirrhosis.

To read the study abstract, click here.

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