Harvoni Is Safe for 3- to 5-Year-Olds With Hepatitis C

Weight-based Harvoni treatment cured almost almost all of a small group of very young people.

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Gilead Sciences' Harvoni (ledipasvir/sofosbuvir) is safe and well tolerated when dosed according to weight among children between age 3 and just shy of 6.

Presenting their findings at the Annual Meeting of the American Association for the Study of Liver Diseases in San Francisco, researchers enrolled 34 children who were older than 3 years old but who had not yet reached their sixth birthday in a study of weight-based dosing of Harvoni.

Thirty-three of the children had genotype 1, including 28 who had genotype 1a and five who had genotype 1b, and one child had genotype 4 of hep C. The participants were enrolled and treated at 21 sites in Australia, Europe and North America. Seventy-one percent of the children were female and 79 percent were white. All had contracted hep C from their mothers and were being treated for the virus for the first time. None of the participants had cirrhosis.

The average age of the children was 4 years old. Their mean body-mass index was 17 kilograms per meter squared, with a range of 13 to 25 kg/m^2. Ten participants weighed less than 17 kg, with a range of 11 to 16 kg and so were prescribed a daily regimen of 33.75 milligrams of the ledipasvir component of Harvoni and 150 mg of the sofosbuvir component. (Sofosbuvir is sold as an individual tablet under the brand name Sovaldi.) The remaining 24 participants weighed 17 kg or greater, with a range of 17 to 34 kg and so were prescribed a daily regimen of 45 mg of ledipasvir and 200 mg of sofosbuvir daily.

The study's first 13 participants underwent extensive analyses of their metabolism of the two drugs in Harvoni. The researchers concluded that the study's weight-based dosing criteria were appropriate for the children.

All the participants were assigned to receive 12 weeks of Harvoni treatment. Thirty-three (97 percent) of the 34 children achieved a sustained virologic response 12 weeks after completing therapy (SVR12, considered a cure).

One child stopped treatment on the fifth day of treatment after vomiting andclaiming that the medication, which could be sprinkled onto food, did not taste good.

No participants experienced a Grade 3 or 4 adverse health event or serious adverse health event.

The most common adverse health events, reported by at least 10 percent of participants, were vomiting, fever, cough, runny nose and strep throat.

To read the conference abstract, click here.

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