Adult antiviral drug effective in suppressing hepatitis B in teens

5 December 2012

A recent clinical trial found that the adult antiviral drug, tenofovir disoproxil fumarate (tenofovir DF), is safe and effective in treating adolescents with hepatitis B virus (HBV). Trial results published in the December issue of *Hepatology*, a journal of the American Association for the Study of Liver Diseases (AASLD), show that tenofovir DF suppressed HBV in 89% of pediatric participants.

Chronic HBV is a major health burden that studies estimate affects 350 million people worldwide, with 600,000 deaths attributed to this chronic disease. The Centers for Disease Control and Prevention (CDC) estimate that more than one million Americans have chronic HBV, with most patients infected during childhood. Medical evidence suggests that 90% of patients infected as infants, and up to 50% infected between one and four years of age develop chronic HBV; 25% of adults who become chronically infected in childhood develop cirrhosis or liver cancer.

"Children chronically infected with HBV are at great risk of developing severe liver disease and possible death due to complications from the disease," said Dr. Karen Murray, Chief of the Division of Gastroenterology and Hepatology at Seattle Children's Hospital in Washington and lead researcher of the clinical trial. "Tenofovir DF is highly effective in treating adults with chronic HBV and our trial evaluated safety and efficacy of the drug in adolescents."

This double-blind, placebo-controlled trial was conducted in 101 adolescents aged 12 to 17 years. Participants were randomized with 52 receiving a daily 300 mg dose of tenofovir DF and 54 taking a placebo for 72 weeks. A virologic response—ability of the antiviral medication to suppress the virus in participants—was the main outcome of this clinical trial. At the onset of the trial 91% of participants tested positive for the hepatitis B e-antigen and 85% received prior HBV therapy.

Researchers observed a virologic response in 89% of participants who received tenofovir DF, while none of the patients in the placebo group achieved HBV suppression. The drug successfully suppressed HBV and normalized alanine aminotransferase (ALT) levels in both adolescents who received no prior treatment and in those previously exposed to HBV therapy. No safety issues, such as a 6% reduction in spine bone density (safety end point), were reported. Trial participants taking tenofovir showed no resistance to the drug.

"Tenofovir DF therapy was well tolerated and effective in suppressing HBV in adolescents," concludes Dr. Murray. "Our trial demonstrates that tenofovir is a beneficial therapy for managing chronic HBV in teens." The authors note that a two-year open-label phase study will further investigate the sustained response and safety of tenofovir DF.

In an editorial also published in Hepatology, Dr. Philip Rosenthal with the University of California, San Francisco (UCSF) questions what can be done to alter the development of liver disease and liver cancer in children with chronic hepatitis B infection. "It was not long ago that drugs to treat HBV were limited and it is gratifying to see an increase in medications to combat this disease being approved for use in children and teens," said Dr. Rosenthal. "While the study by Murray et al. was limited to adolescents, future study of tenofovir DF in younger children is underway."

More information: "Randomized, Placebo-Controlled Trial of Tenofovir Disoproxil Fumarate in Adolescents with Chronic Hepatitis B." Karen F. Murray, Leszek Szenborn, Jacek Wysocki, Stephen Rossi, Amoreena C. Corsa, Phillip Dinh, John McHutchison, Phillip S. Pang, Luminita M. Luminos, Malgorzata Pawlowska and Jacek Mizerski. Hepatology; (DOI: 10.1002/hep.25818); Print Issue Date: December, 2012.

Provided by Wiley

APA citation: Adult antiviral drug effective in suppressing hepatitis B in teens (2012, December 5) retrieved 11 October 2022 from https://medicalxpress.com/news/2012-12-adult-antiviral-drug-effective-suppressing.html