Investigational Hepatitis E Vaccine Found To Completely Block Disease

Researchers from Xiamen University, China, reported in the Lancet that in a large randomised trial involving more than 100,000 participants, an investigational vaccine (HEV 239 or Hecolin) against hepatitis E was shown to be completely effective. None of the patients who received the full three doses of the vaccine developed hepatitis E over a 12-month follow up. In contrast, there were 15 cases of hepatitis E among the participants who were given hepatitis B vaccine in the placebo arm. When the analysis included participants who received two doses, the vaccine efficacy was the same. Among those who got one dose, the vaccine efficacy was 95.5%.

The researchers stated that research into the hepatitis E virus has largely been neglected, even though the virus is widespread (with estimates suggesting that one-third of the people around the world are infected) and can cause serious disease and death. They thus decided to test the efficacy of the vaccine in a double blind, randomised, placebo-controlled trial, conducted from August 2007 to June 2009, in Jiangsu province, China, where the virus is endemic. For the main study, 56,302 volunteers were randomly assigned to receive three intramuscular vaccine doses (baseline, one month, and six months). In a placebo group, 56,302 received a hepatitis B vaccine (same vaccination schedule). In each of the two groups, 86% received all three doses, and were followed for 12 months (beginning 31 days after the last dose).

After follow-up, there were no cases of hepatitis E in the vaccine group, while there were 15 cases in the placebo arm. In addition, five additional participants in the placebo group developed hepatitis E during a period from 14 days after the second dose and before the third dose (producing an efficacy rate of 100% for two doses). Of the entire cohort, there were 23 cases of hepatitis E during follow-up. This included one case in the vaccine group who had received one dose, and 22 cases in the placebo group (producing an efficacy rate of 95.5% for one dose).

The researchers state that the high efficacy rate after two doses suggests that the vaccine can be deployed quickly and effectively in the context of an outbreak, or for people travelling to an endemic area.

The adverse events were local and mild – mainly pain and swelling at the injection site. The researchers state that while the vaccine was well tolerated and effective among a general adult population, further studies are needed to assess the safety and effectiveness in pregnant women, for people <15 years old, and for people > 65 years old.

In an accompanying commentary, it was stated that a safe, effective and affordable vaccine raises the prospect of routine vaccination to reduce the impact of chronic hepatitis E, and reduce epidemic outbreaks. Vaccines should not be a substitute for improvements in sanitation, but given that sanitary improvements in many places have been slow to occur, the vaccine would be the best new stop-gap measure to control hepatitis E.

Two of the authors are employees of the company that is developing the vaccine. SMA

Sources: (1) Zhu FC, et al. Efficacy and safety of a recombinant hepatitis E vaccine in healthy adults: a large-scale, randomised, double-blind placebo-controlled, phase 3 trial. Lancet 2010; DOI: 10.1016/S0140-6736(10)61030-6. (2) Holmberg SD. Hepatitis E vaccine: not a moment too soon. Lancet 2010; DOI: 10.1016/S0140-6736(10)61260-3.