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Paper

Ten-year neonatal hepatitis B vaccination program, the Netherlands, 1982–1992: protective efficacy and long-term immunogenicity

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Abstract

From 1982 to 1989, 705 infants born to HBsAg-positive mothers entered the Dutch neonatal hepatitis B vaccination program and received passive-active hepatitis B immunization in three randomized controlled trials testing variations in time of starting active vaccination, dose and type of vaccine, and number of hepatitis B immunoglobulin (HBIg) injections. A meta-analysis of individual patient data of the three randomized trials was performed to determine which independent host and vaccination related factors influence protective efficacy and long-term immunogenicity, and to assess whether hepatitis B vaccination concomitant with standard DKTP vaccination provides optimal protection. Statistical methodology included multivariate logistic regression analysis. Eight infants (1.1%), all born to HBeAg-positive mothers, became HBsAg carriers within the first year of life. The protective efficacy rate (PER) of passive-active

immunization at 12 months follow-up was 92% for the total group of children from 114 HBeAg-positive mothers with no significant differences between children starting active immunization at birth or at 3 months of age, between infants starting at 3 months of age receiving one or two doses of HBIg or between those receiving plasma derived or recombinant vaccine. The only factor that affected the PER significantly was the level of maternal HBV DNA; PER was 100% if maternal HBV DNA was <150 pg ml^{-1} and 68% for HBV DNA levels > 150 pg ml^{-1}. After 5 years of follow-up, the group that started active immunization at birth had significantly more infants with loss of seroprotection (anti-HBs levels < 10 IU l^{-1}, 15%) than the corresponding group starting at 3 months of age (anti-HBs < 10 IU l^{-2}, 2%). One of 35 children with loss of seroprotection at 2 years became a HBsAg carrier in the fifth year of follow-up. This meta-analysis shows that the protective efficacy of passive-active hepatitis B vaccination is mainly influenced by material HBV DNA levels, and independent of the time of starting active vaccination at birth or at 3 monts of age; long-term immunity was enhanced by starting active vaccination concomitant with DKTP vaccination. These findings allow incorporation of hepatitis B vaccine into the standard infant immunization programs for countries with a passive-active immunization strategy for the control of hepatitis B. Additional measures are needed to protect neonates of highly viremic women.

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Keywords

hepatitis B; vaccine plasma; hepatitis B immunoglobulin; recombinant; neonates; meta-analysis; randomized conrolled trials

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