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Titel des Beitrags: Concomitant administration of a virosome-adjuvanted hepatitis A vaccine with routine childhood vaccines at age twelve to fifteen months: a randomized controlled trial.

Abstract: BACKGROUND: The objectives of this trial were to test for noninferiority of a virosomal hepatitis A virus (HAV) vaccine (Epaxal) coadministered with routine childhood vaccines compared with Epaxal given alone and to an alum-adjuvanted HAV vaccine (Havrix Junior) coadministered with routine childhood vaccines. METHODS: Healthy children 12- to 15-month-old were randomized to receive either a pediatric dose (0.25 mL) of Epaxal coadministered with DTPaHibIPV, oral polio vaccine, and measles-mumps-rubella vaccine (n = 109; group A), or Epaxal given alone (n = 105; group B), or Havrix Junior coadministered with DTPaHibIPV, oral polio vaccine, and measles-mumps-rubella vaccine (n = 108; group C). A booster dose was given 6 months later. Anti-HAV antibodies were tested before and 1 month after each vaccination. Safety was assessed for 1 month after each vaccination. Solicited adverse events were assessed for 4 days after each vaccination. RESULTS: HAV seroprotection rates (> or =20 mIU/mL) at 1 and 6 months after first dose were: A: 94.2% and 87.5%, B: 92.6% and 80.0%, C: 78.2% and 71.3%, respectively (A versus C: P< 0.001 and P = 0.017 at month 1 and 6, respectively). The respective...
geometric mean concentrations were: A: 51 and 64 mIU/mL, B: 49 and 59 mIU/mL, C: 33 and 37 mIU/mL (A versus C: P< 0.001 at both time points). All groups achieved 100% seroprotection after the booster dose. The geometric mean concentrations after the booster dose were 1758, 1662, and 1414, for groups A, B and C, respectively (A versus C: P = 0.15). No clinically significant reduction in immune response to all concomitant vaccine antigens was seen. All vaccines were well tolerated.

CONCLUSIONS: Coadministration of pediatric Epaxal with routine childhood vaccines showed immunogenicity and safety equal to Epaxal alone as well as to Havrix Junior. After first dose, Epaxal was significantly more immunogenic than Havrix Junior.

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