Long Term Efficacy of Hepatitis B Vaccination of Newborns from HBs Ag positive Mothers in Thailand

2006 review

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Study details

• Interim analysis of long-term follow-up of 3 clinical trials

• Newborns from either
  – HBsAg + and HBeAg +
  – HBsAg + and HBeAg -
  – HBsAg - and HBeAg -

• Vaccination with Engerix B 10 µg, starting at birth
  – 2 vaccination schedules: 0, 1, 2, 12 months or 0, 1, 6 months

• Some groups received HB Ig at birth, some not
• Some groups were boosted at 5 years, some not
• Long time follow-up:
  – Yearly blood sample for analysis of anti HBs, HBs Ag and anti HBc
  – Some samples analyzed by PCR

• Studies ongoing, different time lines: between 14 and 17 year follow-up available
Study HBV 064: Long-term follow-up: HBs Ag

G1: schedule 0-1-2-12-60, HBsAg+ and HBeAg+ mothers
G2: schedule 0-1-2-12, HBsAg+ and HBeAg+ mothers
G3: schedule 0-1-2-12-60, HBsAg+ and HBeAg - mothers
G4: schedule 0-1-2-12, HBsAg+ and HBeAg - mothers
G5: schedule 0-1-2-12-60, HBsAg - and HBeAg - mothers
G6: schedule 0-1-2-12, HBsAg - and HBeAg - mothers
Efficacy data: sample size

- 423/428 enrolled subjects had immuno data
  - 40 subject: not enough data available to conclude (no long term data available)
- 236 subjects are followed-up until at least year 14
- Study ongoing, so far 108 subjects until year 17 in current analysis

- 244 subjects: initial serological markers of hepatitis B which disappear over time
  - Compatible with maternal antibody transfer and/or mild ante- or peri- natal infection without full blown immune response
8 subjects (< 2%) had serological markers that can be compatible with chronic infection

- All show chronic HBs Ag and anti HBc positivity from time of primary vaccination onwards
  - (1/8 becomes HBsAg positive at month 24)
- 3/8 had no immune response
- 4/4 of tested subjects were DNA positive at Y10 to 18

- No new chronic infections after month 24
7 subjects had serological markers that can be compatible with acute infection before vaccination

- anti HBc positive at screening and chronically thereafter
- HBs Ag negative
- All mounted an adequate immune response (> 10 mIU/ml)
Conclusions

• Vaccination of newborn from HBsAg positive mothers is effective
  – only 8 subjects (<2%) develop chronic infection
  – none of them after month 24

• Sporadic appearance of serological markers
  – No clinical significance detected
  – Further analysis warranted
    • confer previous VHPB