

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

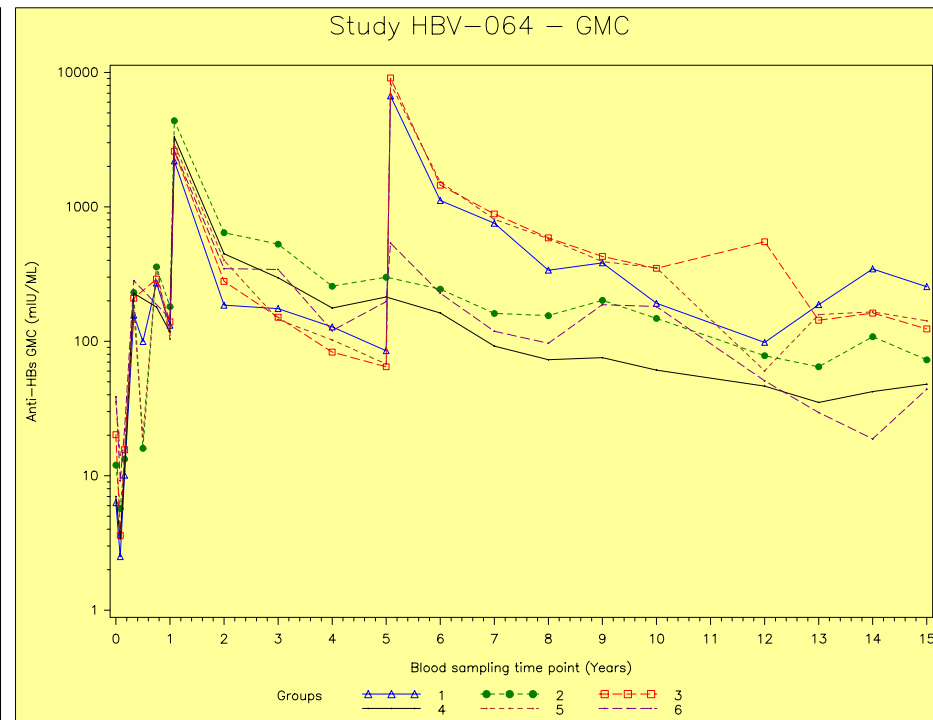
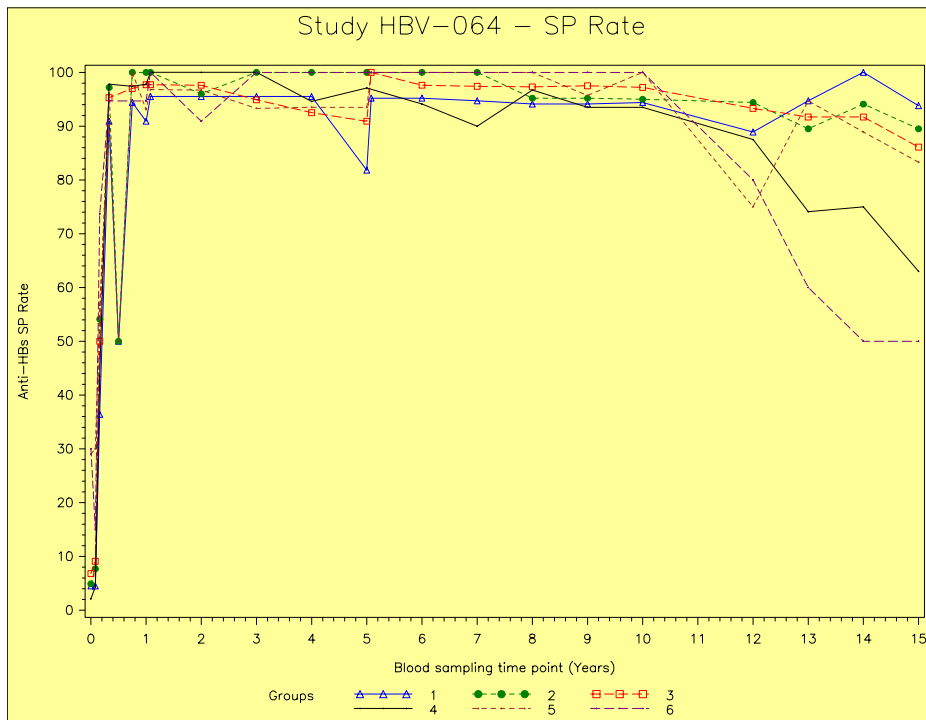
2006 review

VHPB, Istanbul, March 2006, B. Hoet, Y. Poovorawan

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,
 G2: schedule 0-1-2-12,
 G3: schedule 0-1-2-12-60,
 G4: schedule 0-1-2-12,
 G5: schedule 0-1-2-12-60,
 G6: schedule 0-1-2-12,

HBsAg+ and HBeAg+ mothers
 HBsAg+ and HBeAg+ mothers
 HBsAg+ and HBeAg - mothers
 HBsAg+ and HBeAg - mothers
 HBsAg - and HBeAg - mothers
 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