

**Hepelisav-B versus Engerix-B in Healthy Adults, Aged 18-55 Years
HBV-10 Trial**

Heplisav-B Vaccine versus Engerix-B Vaccine in Healthy Adults Aged 18-55 Years HBV-10 Trial: Design

- **Design**

- Phase 3 observer-blinded randomized controlled trial to compare the safety and efficacy of Heplisav-B versus Engerix-B in healthy adults

- **Participants**

- Ages 15-55 years[^]
- HBV vaccine naïve
- Exclusions: HBV*, HIV, pregnancy (or lactation), autoimmune or other clinically significant illness, immunosuppressed

- **Setting**

- Multiple centers in Canada and Germany

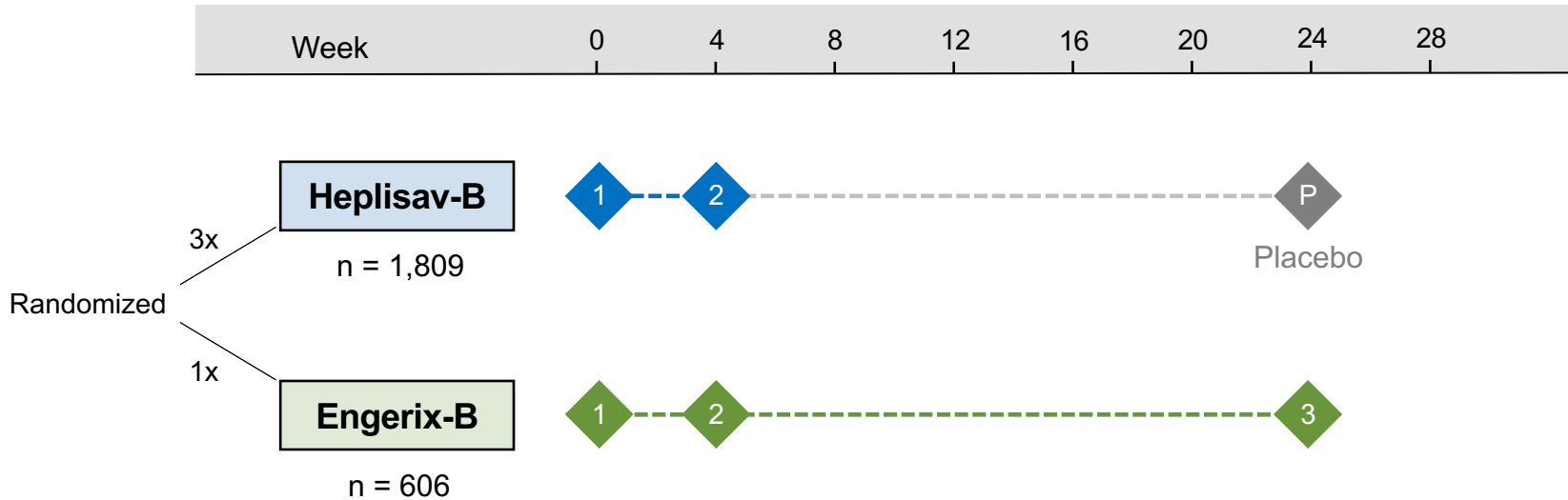
- **Study End-Point**

- Seroprotection = anti-HBs level ≥ 10 mIU/mL

[^]Adolescents age 11-17 years were eligible, but most had previously received HBV vaccine as child as part of universal vaccine program.

*Any positive for HBsAg, anti-HBs, or anti-HB core

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Vaccine Dosing

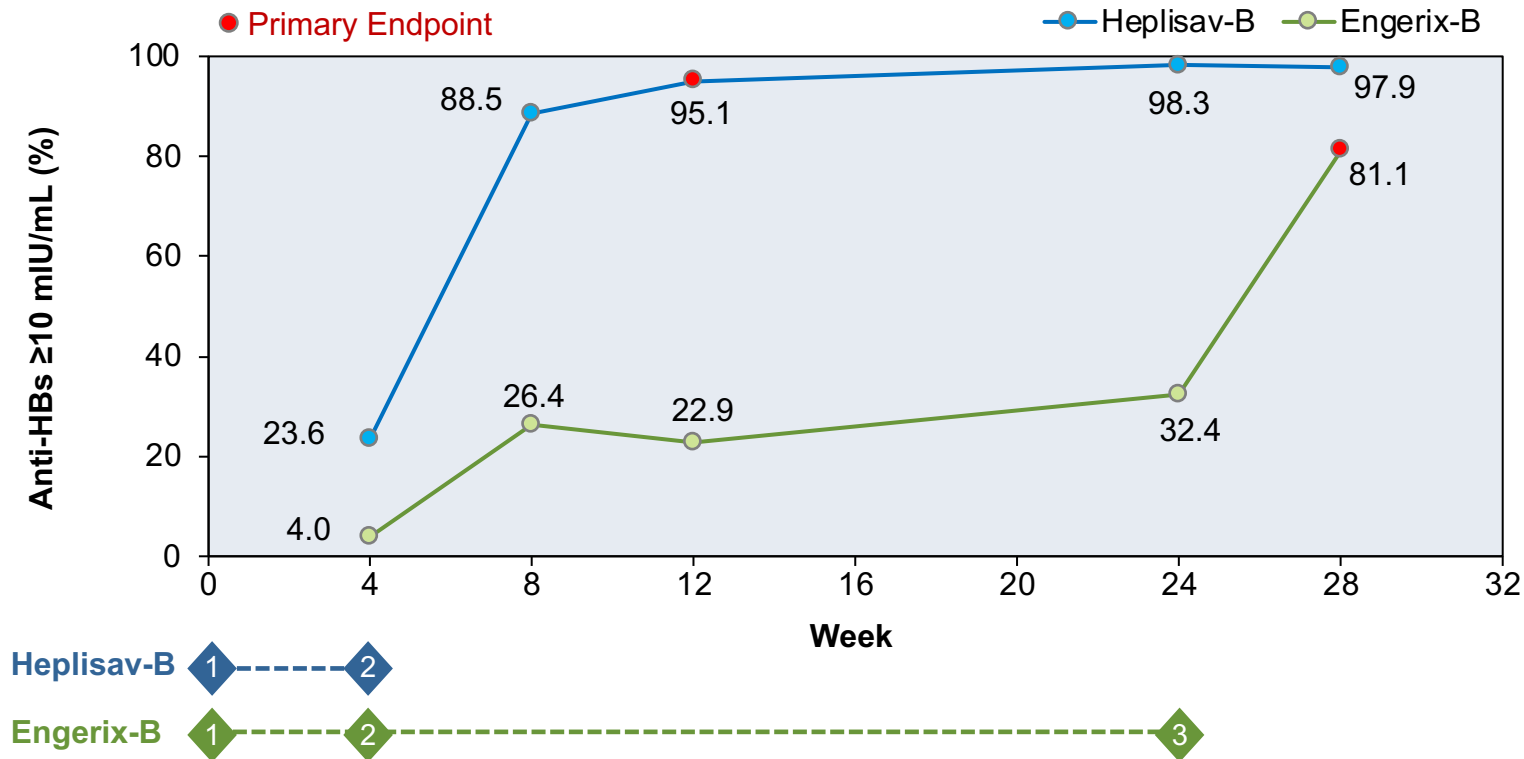
Heplisav-B: 0.5 mL dose of 3 mg CpG 1018 adjuvant with 20 mcg recombinant HBsAg at week 0 and 4, followed by administration of saline placebo at week 24

Engerix-B: 1 mL dose of 20 mcg recombinant HBsAg at week 0, 4 and 24

Heplisav-B Vaccine versus Engerix-B Vaccine in Healthy Adults Aged 18-55 Years HBV-10 Trial: Baseline Characteristics

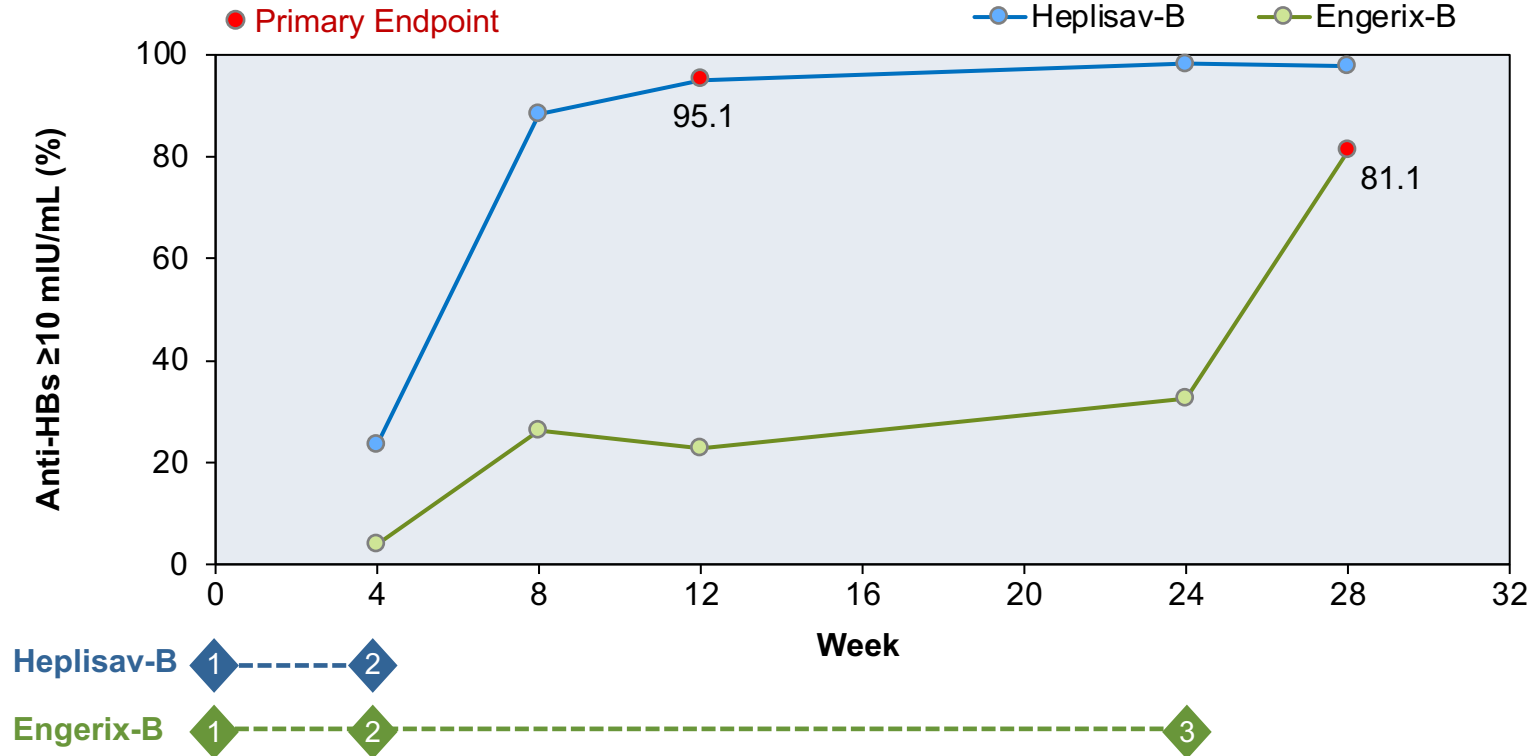
Baseline Characteristic	Heplisav-B (n = 1,809)	Engerix-B (n = 606)
Age, mean (range), years	40 (18-55)	40 (18-55)
Male, no. (%)	852 (47)	262 (43)
Race, no. (%)		
White	1,690 (93)	556 (92)
Black	39 (2)	20 (3)
Asian	43 (2)	22 (4)
Other	37 (3)	8 (1)
Weight, mean (range), kg	80.3 (43-173)	80.8 (39-179)
Body mass index, kg/m ²	27.4 (15.0-58.1)	27.6 (16.4-63.2)
Smoker, n (%)	654 (36)	224 (37)

Heplisav-B Vaccine versus Engerix-B Vaccine in Healthy Adults Aged 18-55 Years HBV-10 Trial: Results



Source: Halperin SA, et al. Vaccine. 2012;30:2556-63.

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Hepelisav-B Vaccine versus Engerix-B Vaccine in Healthy Adults Aged 18-55 Years HBV-10 Trial: Conclusions

Conclusions: “A short, two-dose regimen of HBV-ISS induced a superior antibody response than a three-dose regimen of a licensed hepatitis B vaccine and was well tolerated.”

This slide deck is from the University of Washington's
Hepatitis B Online and *Hepatitis C Online* projects.

Hepatitis B Online

www.hepatitisB.uw.edu

Hepatitis C Online

www.hepatitisC.uw.edu

This project is funded by the Centers for Disease Control and Prevention (CDC)
Cooperative Agreement (CDC-RFA- PS21-2105)