

T-cell responses to Pre-S1 and Pre-S2 are correlated to anti-HBs antibody titers, which are higher and persist longer in volunteers vaccinated with 3-antigen vs. 1-antigen hepatitis B vaccine

F. DALZARTOMAI, E. VERRARI, E. BERTHOUD, D. PLASSER, J.C. ANDERSON, V. POPONCE

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Introduction

- **Preferid®** is a 3-antigen HBV vaccine that contains three distinct HBV surface antigens (S, Pre-S1, and Pre-S2), is adjuvanted with alum, and is produced in mammalian CHO cells - the conventional HBV vaccine is single-antigen (S only) and is yeast-derived.
- Pre-S1 and Pre-S2 proteins serve important roles in the viral invasion of hepatocytes, and in viral infection, viral assembly, viral replication, and stimulation of immune responses in the body.¹ Additionally, Pre-S1 antigens have CD4⁺ T-cell epitopes that may mediate improved antibody responses against HBsAg, activating both cellular and humoral immune responses.
- **PROTECT** was a multicenter, randomized, Phase 3 randomized controlled trial comparing immune responses and safety of Preferid to a widely used single-antigen vaccine (Engerix-B®) in adults. In 10 countries, the U.S., and Canada. Seroprotection rate (SPR) and geometric mean concentration (GMC) of anti-HBs were assessed for 12 months.²
- After the completion of PROTECT, the lead investigator-initiated follow-up studies to assess long-term persistence of anti-HBs from 2.5 and 3.5 years after the 1st dose in participants enrolled in Finland.
- Data presented in this poster are the result of a further analysis comparing T-cell and antibody responses to Pre-S1, Pre-S2, and S antigens in participants vaccinated with Preferid® and Engerix-B® at timepoints during both the PROTECT and follow-up studies.

Poster abstracts to be published on 11-16 June 2023 at EASL 2023. Abstracts are available in the EASL 2023 Abstract Book.

Method & Objectives

PROTECT Phase 3 Study (N=1000)	
Study Population (N)	1000 participants
Age Range	18-70 years
Gender	~50% male
Randomized	Yes (1:1 ratio, Preferid® vs. Engerix-B®)
Study Site (Country)	10 sites (10 countries)
Duration	12 months (up to 12 weeks)
Study Endpoints	Seroprotection rate (SPR)
Primary Endpoints	SPR at Day 12
Secondary Endpoints	SPR at Day 12, 24, 48, 72, 96, 120, 144, 168, 192, 216, 240, 264, 288, 312, 336, 360, 384, 408, 432, 456, 480, 504, 528, 552, 576, 600, 624, 648, 672, 696, 720, 744, 768, 792, 816, 840, 864, 888, 912, 936, 960, 984, 1008, 1032, 1056, 1080, 1104, 1128, 1152, 1176, 1200

- A subset of participants (N=400) from the PROTECT study were vaccinated with 3 doses of either Preferid® or Engerix-B®. T-cell responses were measured at pre- and post-vaccination timepoints.
- In separate investigator-initiated follow-up study, antibody titer was tested in an additional subset of volunteers 3.5 years post-vaccination.
- T-cell responses were measured with a 16 day culture (Pre-S1, Pre-S2, and S antigens) in the presence of Pre-S1, Pre-S2 or HBsAg peptides (SPR peptides) and HLA-2.
- **Objective:** To assess the potential relationship between T-cell responses induced with 3-antigen (Preferid®) and 1-antigen (Engerix-B®) HBV vaccines and the magnitude and persistence of antibody responses up to 3.5 years after the completion of vaccination.

Conclusions

- The 3-antigen HBV vaccine, Preferid®, induces significant T-cell responses to the Pre-S1 domain after 2 vaccinations.
- Preferid® and Engerix-B® with equivalent T-cell responses against HBsAg after 2 or 3 vaccinations.
- After 2 vaccinations of Preferid®, T-cell responses elicited against both Pre-S1/2 and HBsAg correlate more strongly with anti-HBs antibody titer vs. HBsAg-specific T-cell responses induced by Engerix-B®.
- At all measured timepoints, anti-HBs antibody titer was significantly higher (P<0.001) in subjects vaccinated with Preferid® vs. those vaccinated with Engerix-B®.
- T-cell responses against the Pre-S1 and Pre-S2 proteins in the 3-antigen HBV vaccine Preferid® correlate with higher anti-HBs antibody titer and may contribute to their greater durability compared to those induced with a 1-antigen HBV vaccine.

Results

Figure 1: Culture-specific (CSP) interferon-γ (IFN-γ) responses to Pre-S1 and Pre-S2 antigens in participants vaccinated with 1-antigen (Engerix-B®) or 3-antigen (Preferid®) HBV vaccines. Significant differences between 1-antigen and 3-antigen vaccines were observed following the second (Day 12) and third (Day 192) vaccinations with Preferid®. Statistically equivalent T-cell responses against the HBsAg peptide were observed after the second and third doses with Preferid® and Engerix-B®.



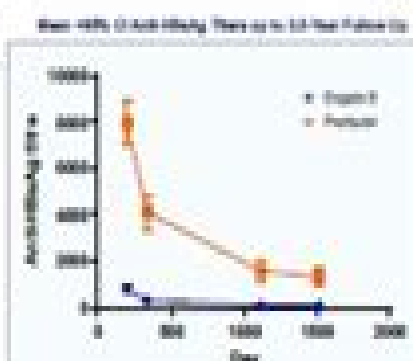
Figure 2: Correlation between Pre-S1 and Pre-S2 T-cell responses at Day 12 and anti-HBs antibody titer at Day 168 following 2 vaccinations with Preferid® (Figure 1).



Figure 3: Correlation between Pre-S1 and Pre-S2 T-cell responses at Day 12 and anti-HBs antibody titer at Day 168 following 3 vaccinations with Preferid® (Figure 1).

Figure 4: Anti-HBs antibody titer during seroprotection (SPR) and Engerix-B® vaccination. The figure shows a line graph of 'Antibody titer' on the y-axis (0 to 10000) and 'Day' on the x-axis (0 to 2000). The graph compares Engerix-B (blue line) and Preferid (red line). Both vaccines show a rapid increase in antibody titer, peaking around Day 100 and then declining. Preferid shows a slightly higher peak and faster decline compared to Engerix-B.

There is a significant difference between the two vaccines. Data presented by Engerix-B® and Preferid® (P<0.001).



References

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2. Jansen, R. J. et al. (2018) *Vaccine* 36, 1000-1008.

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Contact information

Dr. Federico Dalzartomai (Chief Medical Officer of IIR Vaccines)
 f.dalzartomai@novartis.com
 Dr. Erika Verrari (Chief Medical Officer of IIR Vaccines)
 e.verrari@novartis.com

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