

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

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1 IIR Barcelona, 2 IIR Barcelona, 3 IIR Barcelona, 4 IIR Barcelona, 5 IIR Barcelona



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 for EASL 2023 will be available from 11-16 June 2023. For more information, please visit www.easl-congress.com.

Method & Objectives

PROTECT Phase 3 Study (N=1000)	
Study Population (N)	1000 participants
Age Range	18-65 years
Gender	~50% Male
Randomized	Yes (1:1 ratio)
Study Site (Country)	10 sites (10 countries)
Duration	12 months (up to 1.5 years)
Study Arms	Preferid® (3-antigen) vs. Engerix-B® (1-antigen)
Primary Endpoints	SPR, GMC
Secondary Endpoints	• Safety (adverse events, serious adverse events) • Reactogenicity (local, systemic) • Immune responses (anti-HBs, anti-HBc) • Reactogenicity (local, systemic)

- 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 titers were tested in an additional subset of volunteers 3.5 years post-vaccination.
- T-cell responses were measured with a 16 day culture (PBMC ELISPOT) in the presence of Pre-S1, Pre-S2 or HBsAg peptides (SP1 peptides) and HLA-D.
- **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® elicit 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-HBsAg antibody titer were 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 (ELISPOT) PBMC ELISPOT responses to HBsAg peptides (S, Pre-S1, and Pre-S2) in subjects vaccinated with 1-antigen (Engerix-B®) or 3-antigen (Preferid®) HBV vaccines. Significant differences between T-cell responses to the Pre-S1 antigen peptide were observed following the second (day 16) and third (day 17) vaccinations with Preferid®. Statistically equivalent T-cell responses against the HBsAg peptide are observed after the second and third doses with Preferid® and Engerix-B®.



Figure 2: Correlation between Pre-S1 and HBsAg T-cell responses at Day 16 and anti-HBs antibody titer at Day 16 following 2 vaccinations with Preferid® (Figure 1).



Figure 3: Correlation between Pre-S1 and HBsAg T-cell responses at Day 17 and anti-HBs antibody titer at Day 17 following 3 vaccinations with Preferid® (Figure 1).

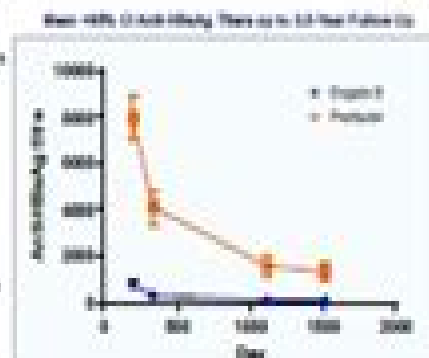
Figure 4: Correlation between Pre-S1 and HBsAg T-cell responses at Day 17 and anti-HBs antibody titer at Day 17 following 3 vaccinations with Preferid® (Figure 1).



Figure 5: Correlation between Pre-S1 and HBsAg T-cell responses at Day 17 and anti-HBs antibody titer at Day 17 following 3 vaccinations with Preferid® (Figure 1).

Figure 6: Anti-HBs antibody titer (IU/ml) over time (Day 0 to Day 180) following 2 vaccinations with Preferid® and Engerix-B®. The graph shows a significant difference between the two groups, with Preferid® maintaining higher titers over time.

There is a significant difference between the two groups in terms of anti-HBs antibody titer (IU/ml) over time (Day 0 to Day 180) following 2 vaccinations with Preferid® and Engerix-B®.



References

1. Wang, T. et al. (2018) *Vaccine* 36(18):2618-2626.
2. Berthoud, E. et al. (2020) *Vaccine* 38(18):2618-2626.

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