

A (VAQTATM)

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= Abstract =

Immunogenicity and Safety of a Two Doses of Hepatitis A Vaccine (VAQTATM) in Healthy Children and Adolescents

Jin Soo Lee, M.D., Ji Ho Park, M.D. and Young Mo Sohn, M.D.

*Department of Pediatrics, Yongdong Severance Hospital, College of Medicine,
Yonsei University, Seoul, Korea*

Purpose : To assess the immunogenicity, safety, and tolerability of hepatitis A vaccine (VAQTATM) in healthy children and adolescents.

Methods : Eligible subjects aged 2 to 17 years received 25 U/0.5 mL of VAQTATM intramuscularly at 0 and 24 week schedule. Bleeds were obtained prior to vaccination and 4 weeks after the second dose to ascertain serostatus. To detect antibody to HAV after vaccination with an inactivated HA vaccine, a modification of the Abbott[®] HAVAB kit was used. Sample with titers ≥ 10 mIU/mL were considered seroconverted. Adverse experiences were monitored.

Results : 102 subjects (54 male, 48 female) were enrolled. The mean age was 6.8 ± 3.5 years. Two subjects were seropositive, two were lost of follow up. 88 subjects were available for a per protocol analysis and 90 for all subjects with serology after the second dose, and ten withdrawal. All subjects (95% CI, 94.8–100) seroconverted. Geometric mean titers was 7,991.1 (95% CI, 6,481.1–9,852.7) with very little difference in per protocol analysis and all subjects analysis. Adverse experiences to VAQTATM were generally mild and transient.

Conclusion : The pediatric two-dose regimen of VAQTATM was found to be highly immunogenic, generally well tolerated and resulted in 100% seroconversion. Regarding Korea is in transition from a high to low risk region resulting in a paradox increase of clinical disease and disease burden, routine vaccination should be considered in order to control hepatitis A effectively.

Key Words : Hepatitis A, Epidemiology, Hepatitis A vaccine, Immunogenicity, Safety

* MSD Korea

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Tel : 02)3497-3354 Fax : 02)3641-9473

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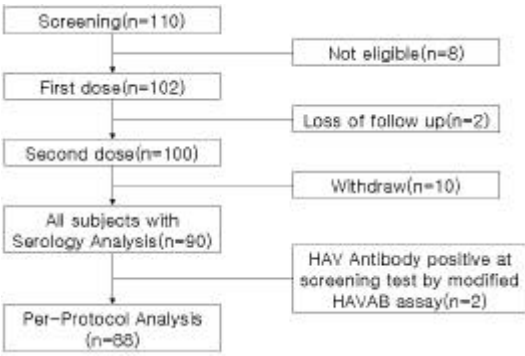


Fig. 1. Diagram for number of subjects.

Table 1. Seropositivity Rate and Geometric Mean Titers

Week 28	SPR	GMT(titer)
PP(n=88)	100%(94.8 100.0)	7,991.1(6,481.2 9,852.7) mIU/mL
AS(n=90)	100%(94.9 100.0)	7,906.4(6,437.2 9,710.8) mIU/mL

PP : Per-protocol analysis, AS : All subjects with serology analysis, SPR : Seropositivity rate, GMT : Geometric mean titer

Table 2. Summary of Adverse Experiences

	Number of subjects
Subjects Entered	102
Subjects follow-up	102(100.0%)
Subjects without adverse experience	0(0.0%)
Subjects with adverse experiences	14(13.7%)
Subjects with vaccine-related adverse experiences	8(7.8%)
Subjects with serious adverse experiences	0(0.0%)
Subjects discontinued due to adverse experiences	0(0.0%)
Subjects died	0(0.0%)

Table 3. Number(%) of Reported Vaccine-related Adverse Experiences (AE) by 14 Days after Injection

	Number of reported subjects(%)		
	First dose	Second dose	Total
Number of subjects	102	100	102
Local reactions	0(0.0%)	3(3.0%)	3(2.9%)
Pain	0(0.0%)	2(2.0%)	2(2.0%)
Pruritus	0(0.0%)	1(1.0%)	1(1.0%)
Systemic reactions	4(3.9%)	2(2.0%)	5(4.9%)
Tinnitus	0(0.0%)	0(0.0%)	0(0.0%)
Diarrhea	0(0.0%)	0(0.0%)	0(0.0%)
Nausea	1(0.9%)	1(1.0%)	2(2.0%)
Vomiting	1(0.9%)	0(0.0%)	1(1.0%)
Cough, Sore throat	0(0.0%)	0(0.0%)	0(0.0%)
Fatigue	3(2.9%)	1(1.0%)	3(2.9%)
Asthenia	1(0.9%)	1(1.0%)	1(1.0%)
Headache	0(0.0%)	0(0.0%)	0(0.0%)

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