

1980 가 . A 가 가 A

가 . A 가 2000 6, 7)

가 A 1997 A 150,000 가 , A

가 1)

A 20 가

A 가 MSD A (VAQTA™)

1982 A 4 6

3%, 7 9 51.1%, 13 15

83.0%, 16 19 93.1% 2). 1989

5 10 30.2%, 10 15

64.7%, 15 20 29.3% 1.

3). 1996 1 5

8.7%, 11 15 1.8%, 16 20 (Institutional Review Boards,

29.3% 4), 1997 IRB)

가 , 5 9

A 0% 10 14 1999 8 2000 4 , 가

2.9% 15 19

15.0% 5).

A 가

, 24 A 가

1996 1 2

81.3%, 5 6 80.0%, 9 10 23.1 ,

%, 13 14 8.3% 15 16 0 ,

% 가 15

A 100% 6

, 14

4).

1995 A

가 가 .

2. A ()
 VAQTA™, CR326F
 0.6 mL 25 U A
 (HAV)
 400 ng
 HAV 가 1
 0.5 mL
 1 24 2
 3.
 1 1, 2 4
 8 10 mL HAV
 , ALT/AST
 HAV
 HAV IgG(HAVAB EIA, Abbott
 Laboratories, IL, USA)
 1 mL -70 mo-
 dified HAVAB IgG Merck Research
 Laboratory(NJ, USA) 가
 (WHO)
 10 mIU/mL
 , (geometric mean titer, GMT)
 가
 4.
 30
 4, 4
 14
 (case report form)
 가

5.
 MS Window PC SAS version
 6.12 PROC STATXACT 3.11
 per-protocol analysis all subjects with
 serology analysis(가
) 가 가
 1 1
 95% 95%
 (itera-
 tive procedure) 8) 가
 1.
 9 110 HAV IgG
 가 1, AST/ALT 3, 3,
 1
 8 102 1
 2 100 2
 (Fig. 1). 2
 90 (All subjects with serol-
 ogy analysis). HAVAB
 2 modified HAVAB
 Per-protocol analysis 88
 2 17 가 54 (52.9%),
 가 48 (47.1%) 6.8

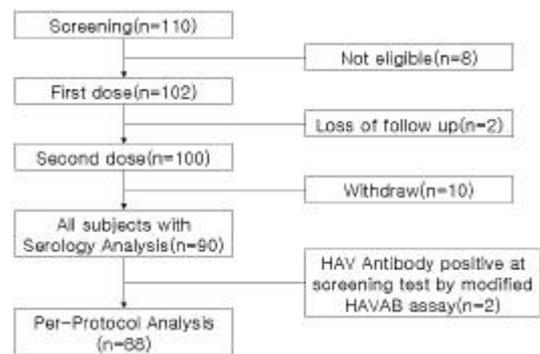


Fig. 1. Diagram for number of subjects.

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%)

2.

2 4 (1 28)

HAVAB modified HAVAB

, per-protocol analysis all subjects with serology analysis 100% . GMT per-protocol analysis 7,991.1 mIU/mL(95% 6,481.1 9,852.7) (Table 1).

3.

14 13.7%

8 7.8%

(Table 2). 3 (2.9%)

2 (2.0%),

1 (1.0%)

2

2

5 (4.9%)

3 (2.9%)

가 가

, 2 (2.0%)

1 (1.0%) (Table 3). 1

1 2

A

80

A

A

A

2 Merck
 modified HAVAB
 2
 4 100%
 가 가 1
 28 가 VAQTA™
 2
 12, 18 6, 가 A
 17), 6 2
 23), 24), 25)
 12, 18
 VAQTA™ 3가 가 A
 16, 20)
 18
 가
 가 A 가
 가
 13 16 26)
 8.3 16.7%가 5) 2001 가 A 가
 가
 20 50% 6, 21)
 2.9% 가 1 가
 1 2 A
 3
 VAQTA™가 HAVRIX™ 2-phenoxye- 가
 thanol 10% 가
 , Guillian-Barre 2 17
 22) 4.9% 가
 가 2
 1

A 가 A
 .
 : A
 , 2 A
 : 110
 24 2 A (VAQTA™)
 . 2 4 modified
 HAVAB 가 , 4
 30 , 14
 가
 : 110 102 1
 , 100 2
 90 2 4 100%
 Per-protocol anal-
 ysis 7,991.1 mIU/mL .
 2.9% 2%,
 1% . 4.2%
 가 2.9% , ,
 : A (VAQTA™) 6
 2 100%
 A

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