

Supplementary Appendix

This appendix has been provided by the authors to give readers additional information about their work.

Supplement to: Jonas MM, Kelley DA, Mizerski J, et al. Clinical Trial of Lamivudine in Children with Chronic Hepatitis B. *N Engl J Med* 2002;346:1706-13.

**SUPPLEMENTARY APPENDIX 1. CHARACTERISTICS
OF THE PATIENTS AT BASE LINE.***

CHARACTERISTIC	PLACEBO GROUP (N=95)	LAMIVUDINE GROUP (N=191)
Age — yr		
Mean	8	9
Range	2–17	1–17
Sex — no. (%)		
Female	34 (36)	68 (36)
Male	61 (64)	123 (64)
Height		
Median — cm	131	135
Range — cm	82–186	86–188
Height-for-age z score	–0.29	–0.09
Weight		
Median — kg	30	32
Range — kg	11–80	13–94
Weight-for-age z score	–0.19	0.02
Racial or ethnic origin — no. (%)		
White	60 (63)	139 (73)
Asian	22 (23)	33 (17)
Black	9 (9)	11 (6)
Hispanic	2 (2)	4 (2)
Other	2 (2)	4 (2)
Route of transmission of HBV infection — no. (%)		
Unknown	39 (41)	89 (47)
Perinatal	36 (38)	61 (32)
Other†	15 (16)	37 (19)
Transfusion	5 (5)	3 (2)
Injection-drug use	0	1 (<1)
Sexual contact	0	0
HBV DNA — meq/ml		
Median	1032	895
Range	1.7–15,010	2.2–28,300
Alanine aminotransferase — no. of times the upper limit of the normal range‡		
Median	2.3	2.1
Range	0.3–22.1	0.7–16.9
Mean	3.2	2.7
Albumin — g/dl§		
Median	4.2	4.1
Range	3.3–4.8	3.5–4.9
Bilirubin — no. of times the upper limit of the normal range¶		
Median	0.3	0.3
Range	0.1–1.4	0.1–4.9
Prior interferon treatment — no. (%)	40 (42)	89 (47)

*There were no significant differences between the groups ($P \geq 0.11$). HBV denotes hepatitis B virus.

†Other routes are routes of horizontal transmission (e.g., family contact, community acquired, and exposure in orphanage).

‡The reference ranges for alanine aminotransferase were 6 to 43 IU per liter for boys and 6 to 34 IU per liter for girls.

§The reference range for albumin was 3.3 to 5.0 g per deciliter.

¶The reference range for bilirubin was 0.2 to 1.2 mg per deciliter.

||One child, who had thalassemia, had an elevated bilirubin level owing to hemolysis.

SUPPLEMENTARY APPENDIX 2. ADVERSE EVENTS THAT OCCURRED IN AT LEAST 5 PERCENT OF PATIENTS.

ADVERSE EVENT	PLACEBO	LAMIVUDINE
	GROUP (N=96)	GROUP (N=191)
	no. (%)	
Ear, nose, and throat infections	41 (43)	47 (25)
Cough	24 (25)	29 (15)
Sore throat	21 (22)	36 (19)
Fever	18 (19)	35 (18)
Headache	17 (18)	34 (18)
Abdominal discomfort and pain	15 (16)	31 (16)
Bronchitis	13 (14)	13 (7)
Nausea and vomiting	10 (10)	18 (9)
Diarrhea	8 (8)	18 (9)
Viral infection	8 (8)	11 (6)
Viral infection of respiratory tract	7 (7)	17 (9)
Malaise and fatigue	7 (7)	15 (8)
Myalgia	7 (7)	13 (7)
Rash	6 (6)	13 (7)
Nasal inflammation	5 (5)	11 (6)
