

# Effects of recombinant alpha interferon on chronic active hepatitis B: preliminary results

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## Abstract

**This paper presents the preliminary results of a study designed to evaluate the effects of alpha interferon in chronic hepatitis B. After six months' treatment with interferon alfa-2b (5 million units (MU), three times weekly) 15 of 25 (60%) patients achieved seroconversion of hepatitis B e antigen, 17 (68%) normalised alanine aminotransferase (ALT) activity, and 15 (60%) showed a decrease in the inflammatory reaction on liver histology. No seroconversions occurred in the control group (n=10), and none of the control patients achieved a normal ALT or showed a reduction in the inflammatory reaction. Adverse effects were experienced by most patients who received interferon but none warranted stopping the treatment.**

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A controlled study was undertaken to evaluate the effects of alpha interferon in patients with liver biopsy proved chronic active hepatitis B (HBV). The preliminary results are presented here.

## Patients and methods

Patients were included in the study if their serum transaminase activities had been greater than twice the upper limit of normal for more than six months and if they were negative for antibodies to hepatitis C virus (HCV), human immunodeficiency virus (HIV), and antibodies to hepatitis B e antigen (HBeAg). They also had to be hepatitis B surface antigen (HBsAg) and HBeAg positive, with chronic active hepatitis on liver histology. Positivity for antibodies to hepatitis delta virus (anti-HDV) was allowed, as was presence of cirrhosis if there was no decompensation.

Treated patients received interferon alfa-2b, 5 million units (MU) intramuscularly three times weekly for six months, while controls

received no treatment. White blood cell and platelet counts were evaluated before treatment and then monthly for 12 months. Efficacy endpoints were given as loss of HBeAg and HBsAg, a return to normal serum alanine aminotransferase (ALT) activities, and improvements in liver histology.

## Results at six months

The characteristics of the 35 patients who completed six months of the study are shown in the Table. Twenty five patients received interferon alfa-2b treatment and 10 were untreated controls. Among the 25 treated patients, 17 (68%) had normal serum ALT activities by the sixth month of interferon treatment and the remaining eight patients (32%) had partial decreases in values. In contrast, none of the controls had normal ALT and only two had partial responses. In patients receiving interferon, mean (SD) serum ALT activities decreased from 141 (99) IU/l before treatment to 42 (26) IU/l after six months of treatment, a statistically significant difference ( $p < 0.05$ , Student's *t* test). One of the responders had chronic active hepatitis associated with cirrhosis.

Fifteen of the 25 (60%) treated patients also became serum HBeAg negative, including one who also lost HBsAg, while none of the controls lost these viral markers. On liver histology, 15 (60%) of those receiving interferon (13 of those who had seroconverted, two who were anti-HDV positive) also had a considerable diminution in the inflammatory reaction, five had no change, and five had progressed. Among the controls, four showed no change and six had progressed.

Adverse effects were experienced by most of the patients who received interferon (including six with hepatitis like illness, 11 with anorexia, 11 with weakness, and 20 with myalgias) but in no case were these serious enough to require stopping treatment.

## Conclusions

These preliminary results indicated that six months of treatment with interferon alfa-2b in patients with chronic active hepatitis B achieved seroconversion of HBeAg in 60%, normal serum ALT values in 68%, and reduced inflammatory reaction in 60% of cases, with no serious adverse effects. None of the controls seroconverted or showed any improvements in liver inflammation.

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TABLE Patient characteristics

	Interferon	Control
Male/female	18/7	7/3
Age (y) (mean (SD))	35.3 (14.5)	36.4 (13.7)
Age range (y)	(17-70)	(24-53)
Heterosexual	25	10
Biopsy: cirrhosis	5	3
Anti-HDV +ve	9	3

HDV=hepatitis delta virus.