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BACKGROUND/AIMS: Alpha-interferon achieves seroconversion in about one third of naive patients. Attempts to achieve seroconversion in patients who have previously failed alpha-interferon have proved disappointing. Combination chemotherapy (alpha-interferon with a nucleoside analogue) might provide a treatment alternative for these patients. We have undertaken a phase 2 study in 20 patients who had previously failed at least one course of alpha-interferon. The study was designed to assess the safety, tolerability and efficacy of the combination. Methods: All patients were treated for 16 weeks with alpha-interferon in combination with 12 or 16 weeks of Lamivudine (3'TC). Patients were followed for 16 weeks post-treatment. Pharmacokinetic studies were performed to identify/exclude significant pharmacokinetic drug interaction. RESULTS: The combination was well tolerated, and side-effects of the combination were indistinguishable from the recognised side-effects of alpha-interferon. Pharmacokinetic studies performed on days 1 and 29 did not show any significant interaction. All patients achieved HBV DNA clearance during treatment, but 19 relapsed at the end of treatment. HBeAg/anti-HBe seroconversion was observed for four patients, but was sustained for a single patient (who also had sustained DNA clearance). CONCLUSIONS: Combination therapy with alpha-interferon and lamivudine given for 16 weeks appears safe and is well tolerated. However, for this group of patients who had previously failed interferon monotherapy, the efficacy of combination interferon/lamivudine therapy appears disappointing, and other treatment strategies should be investigated.

Publication Types:

- Clinical Trial
- Clinical Trial, Phase II
- Controlled Clinical Trial
- Randomized Controlled Trial

PMID: 9672165 [PubMed - indexed for MEDLINE]