Recombinant Interferon–beta–1a Plus Ribavirin in the Treatment of Chronic Hepatitis C: A Prospective, Randomised, Comparative Pilot Study

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Background/Objectives: Despite the advancement of treatments for chronic HCV infection, approximately 20% and 50% of patients with HCV genotype 2 or 3 and genotype 1 respectively are unable to achieve sustained virological response (SVR). Interferon (IFN)–beta has been shown to have anti–viral activity, which may be of use in treating viral infections. A recent publication has shown that Asian patients may benefit from IFN–beta treatment as compared to Caucasian patients. The objective of this pilot study is to compare the safety and efficacy of IFN–beta (44 mcg, Serono) plus ribavirin and IFN–alpha (3 MIU) plus ribavirin in the treatment of patients with chronic HCV infection. This report provides the end–of–treatment (ETR) outcome after 24 weeks of treatment.

Materials/Methods: A total of 20 eligible patients were randomised in equal proportion to receive one of the study treatments. The main eligibility criteria were confirmation of chronic HCV infection by PCR, exclusion of other causes of liver disease and adequate bone marrow reserve. The treatment regimen consisted of 24 weeks of treatment (IFN given subcutaneously 3 times a week and ribavirin given orally at 1000–1200 mg/day) and 24 weeks of observation period. Patients who did not achieve early virological response (defined as a decreased of at least 2 log viral load from baseline) at treatment week 12 were classified as non–responder and discontinued from the treatment but continued with the observation period.

Results: At ETR, 6 patients (60%) and 4 patients (40%) in the IFN–beta group and IFN–alpha group respectively achieved viral clearance. An average of 6 and 9 adverse events (AEs) were reported in the IFN–beta group and IFN–alpha group respectively. Majority of the AEs were mild. Two severe AEs (headache and general weakness) were reported in the IFN–alpha group and none in the IFN–beta group. It is interesting to note that the baseline viral load in the IFN–beta group was higher (p=0.057) than that in the IFN–alpha group and the IFN–beta group had more HCV genotype 1 patients (8 versus 7 in the IFN–alpha group).

Conclusions: This pilot study indicates that recombinant IFN–beta combination with ribavirin may be an alternate treatment option in chronic HCV infected patients. The safety and efficacy of IFN–beta were comparable to IFN–alpha treatment. A larger prospective study will be required to confirm the current findings.