1. Infections (including Viral Hepatitis)

Reference

Sata M, Amagase H, Koga S, et al. Therapeutic effect of IFN-β (Feron) plus shosaikoto combination therapy on chronic active hepatitis B*. *Rinsho to Kenkyu* (*Japanese Journal of Clinical and Experimental Medicine*) 1994; 71: 814-20 (in Japanese). Ichushi Web ID: 1994141311

1. Objectives

To evaluate the therapeutic effect of interferon (IFN)-beta plus shosaikoto (小柴胡湯) on chronic active hepatitis B.

2. Design

Randmized controlled trial using sealed envelopes for allocation (RCT-envelope)

3. Setting

Nine university hospitals and 15 general hospitals, Japan.

4. Participants

Sixty-two patients who presented with chronic active hepatitis on liver biopsy histology (obtained within a year of symptom onset) and were positive for both HBsAg and HBeAg.

5. Intervention

Arm 1: treatment with IFN-β (total dose 102×10^6 IU) for 8 weeks + shosaikoto (小柴胡湯) (manufacturer, not specified) 2.0 g or 2.5 g t.i.d. for 8 weeks and 6 months (n=28).
Arm 2: treatment with IFN-β alone (total dose 102×10^6 IU) for 8 weeks (n=34).

6. Main outcome measures

Blood levels of HBsAg, HBeAg, HBeAb, and HBV-DNA-polymerase (DNA-P), blood biochemistry, and urinalysis. These variables were examined 4 weeks before the start of the treatment; on day 1 and weeks 1, 2, and 4 of the treatment, at the end of the treatment, and 1, 2, 3, 4, 5, 6, 9, and 12 months after the completion of the treatment.

7. Main results

Treatment was discontinued in 3 patients in arm 1 and 8 patients in arm 2. After the IFN-β therapy, there were no significant between-arm differences in DNA-P reduction, clearance rate, other changes over time, clearance of HBeAg, rate of HBeAg seroconversion (SC), and time course of serum ALT and AST levels. In 12 patients who cleared HBeAg at 12 months after the completion of IFN-β therapy, AST level tended to be lower in the shosaikoto-combined group. There were no significant between-arm differences in blood biochemistry findings.

8. Conclusions

IFN plus shosaikoto and IFN alone had similar efficacy for chronic hepatitis B.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Treatment was not discontinued due to adverse drug reactions in either arm. Hematemesis developed in one patient in the IFN alone group but resolved with antiulcer drug treatment. The causal relationship between this event and the intervention is not clear. The event may be attributed to NSAIDs (non-steroidal anti-inflammatory drugs) use.

11. Abstractor's comments

The authors of this study deserve praise for conducting an RCT in a multicenter setting. The report would have been more informative if it included evaluation of subjective symptoms and long-term outcomes, in addition to the results of virological examinations.

12. Abstractor and date

Kogure T, 8 August 2008, 1 June 2010.