

1. Infections (including Viral Hepatitis)**Reference**

Nakajima O, Sone M. Interferon plus shosaikoto combination therapy for chronic hepatitis C (the first report) - effectiveness in reducing adverse effects of interferon-*. *Rinsho to Kenkyu (Japanese Journal of Clinical and Experimental Medicine)*. 1993; 70: 2994-3002 (in Japanese). Ichushi Web ID: 1994049432

1. Objectives

To evaluate the efficacy of shosaikoto (小柴胡湯) for reducing the adverse effects of interferon in patients with chronic hepatitis C.

2. Design

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

3. Setting

Single institution (National Okura Hospital; current National Center for Child Health and Development), Japan.

4. Participants

Forty-eight patients with chronic hepatitis C.

5. Intervention

Arm 1: treatment with interferon-alpha 6 million units daily for 2 weeks, then three times weekly + Kanebo Shosaikoto (小柴胡湯) Extract Fine Granules 2 g t.i.d. (n=24).

Arm 2: treatment with interferon alone (n=24).

Duration of treatment: at least 12 months.

6. Main outcome measures

Subjective symptoms including fever and laboratory findings including blood cell counts.

7. Main results

Both the severity and frequency of fever were significantly lower in arm 1. Leukopenia at 1 month was significantly reduced in arm 1. There was no significant between-arm difference in the occurrence of other adverse drug reactions.

8. Conclusions

Shosaikoto may reduce adverse effects of interferon.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Not mentioned.

11. Abstractor's comments

This is the first report on a clinical trial of interferon plus shosaikoto combination therapy for chronic hepatitis C, summarizing only the part related to the occurrence of adverse drug reactions. Interestingly, shosaikoto, which is also used for treating *sho-kan* (傷寒, cold damage), reduces the “*sho-kan* -like” adverse effects of interferon.

12. Abstractor and date

Oikawa T, 19 September 2008, 1 June 2010.