

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

Sone M, Nakajima O. Evaluation of the usefulness of shosaikoto in the treatment of chronic hepatitis C after interferon therapy*. *Rinsho to Kenkyu (Japanese Journal of Clinical and Experimental Medicine)* 1995; 72: 3193-7 [in Japanese]. Ichushi Web ID: 1996190408 [MOL](#), [MOL-Lib](#)

Nakajima O, Sone M. Evaluation of the usefulness of shosaikoto in the treatment of chronic hepatitis C after interferon therapy - the second report-*. *Rinsho to Kenkyu (Japanese Journal of Clinical and Experimental Medicine)* 1998; 75: 1883-8 (in Japanese). Ichushi Web ID: 1999004032 [MOL](#), [MOL-Lib](#)

1. Objectives

To evaluate the efficacy and safety of shosaikoto (小柴胡湯) in chronic hepatitis C after interferon (IFN) therapy.

2. Design

Randomized controlled trial (RCT).

3. Setting

One general hospital, Japan.

4. Participants

One hundred and one patients with chronic active hepatitis C who completed IFN therapy.

5. Intervention

Arm 1: IFN therapy (for 6 months) and then administration of liver protector (for 6 months), followed by treatment with Kanebo Shosaikoto (小柴胡湯) Extract Fine Granules 2.0 g t.i.d. 30 minutes before meals for 24 months (n=49).

Arm 2: IFN therapy and then administration of liver protector, followed by continued treatment with liver protector for 24 months (n=52).

6. Main outcome measures

Liver function test, time course of hepatitis C virus (HCV)-RNA level, time course of platelet and white blood cell counts.

7. Main results

Alanine aminotransferase (ALT) level was not significantly different between arms 1 and 2 at 24 months. Aspartate aminotransferase (AST) level and HCV-RNA level were significantly reduced in arm 1 compared with arm 2 at 24 months ($P<0.05$).

8. Conclusions

Shosaikoto is effective as maintenance therapy following IFN treatment for chronic hepatitis C.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Platelet count was significantly different between arms 1 and 2 ($P<0.05$); it was reduced compared with the baseline level in arm 2. White blood cell count was also significantly different between arms 1 and 2; it was reduced, but not significantly different from the baseline level in arm 2. The tendency toward pancreatic dysfunction after the IFN therapy was improved earlier in arm 1 than in arm 2.

11. Abstractor's comments

This is a clinically, highly significant study in that long-term follow-up was conducted in an RCT. Furthermore, between-arm comparisons were sufficient. This study provides high-level evidence.

12. Abstractor and date

Kogure T, 8 August 2008, 31 December 2013.