

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

Nakajima O, Sone M, Kurokawa K, et al. The Complementary treatment for chronic hepatitis C. *Kagaku Ryoho Kenkyusho Kiyo (Bulletin of the Institute of Chemotherapy)* 2003; 34: 40-51 (in Japanese with English abstract). Ichushi Web ID: 2004188041

1. Objectives

To confirm the efficacy of shosaikoto (小柴胡湯) for interferon-resistant chronic hepatitis C.

2. Design

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

3. Setting

One university hospital and general hospitals, Japan.

4. Participants

One hundred patients with chronic active hepatitis C who completed interferon therapy.

5. Intervention

Arm 1: treatment with squalene 1500 mg/day.(n=33)

Arm 2: treatment with cepharanthine (1 mg/kg body weight per day). (n=33)

Arm 3: treatment with shosaikoto (小柴胡湯) 6.0 g/day. (n=34)

In all arms, study drugs were orally administered in three divided daily doses before meals for 5 years.

6. Main outcome measures

Levels of aspartate aminotransferase (AST), alanine aminotransferase (ALT), procollagen III peptide (PIIP), type IV collagen, and hepatitis C virus (HCV)-RNA.

7. Main results

AST and ALT showed overall significant decreases, except for transient elevations after 6 and 30 months of treatment. Type IV collagen, PIIP, and HCV-RNA also decreased significantly in all arms. No significant differences in these variables were observed among the three arms. AST and ALT were significantly decreased at 50 months in arm 3, but not in arms 1 and 2. Choline esterase (Ch-E) did not change in arm 3, but decreased significantly in arms 1 and 2. Type IV collagen and HCV-RNA decreased significantly in arm 3 and increased significantly in arms 1 and 2. Changes in PIIP were similar to those of type IV collagen.

8. Conclusions

Shosaikoto is effective for the treatment of chronic hepatitis C and its efficacy is equivalent to that of squalene or cepharanthine.

9. From Kampo medicine perspective

One patient with “*in-sho* (陰証, yin pattern)” and “*kyo-sho* (虚証, deficiency pattern)” was excluded before the allocation, and the study was actually conducted in 99 patients.

10. Safety assessment in the article

None.

11. Abstractor's comments

This study confirmed the efficacy of shosaikoto for the treatment of chronic hepatitis C.

12. Abstractor and date

Kogure T, 15 June 2007, 1 April 2008.