

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

Isai H. Efficacy of Kampo formulations for reducing adverse effects of interferon therapy in patients with chronic hepatitis C\*. *Shindan to Chiryō (Diagnosis and Treatment)* 1996; 84: 1505-9 (in Japanese). [MOL](#), [MOL-Lib](#)

**1. Objectives**

To evaluate the efficacy of Kampo formulations for reducing adverse effects of interferon therapy in patients with chronic hepatitis C.

**2. Design**

Randomized controlled trial (RCT).

**3. Setting**

Single hospital (Hokkaido Kosei-ren Mukawa Kosei Hospital), Japan.

**4. Participants**

Twelve patients with chronic hepatitis C.

**5. Intervention**

Arm 1: treatment with interferon-alpha 6 million units daily on days 1–3 and 10 million units daily on days 4–14, then 10 million units 3 times weekly for 12 weeks + Kampo formulation (TSUMURA Keishito [桂枝湯] Extract Granules 5 g, TSUMURA Maoto [麻黄湯] Extract Granules 5 g, and TSUMURA Kojinmatsu [紅参末] 4 g) daily from the first day of interferon therapy and continuing for 4 weeks (n=6).

Arm 2: treatment with interferon alone (n=6).

**6. Main outcome measures**

Body temperature, subjective symptoms, blood biochemistry, and usage of diclofenac sodium suppository.

**7. Main results**

During first 4 weeks, usage of diclofenac sodium suppository was significantly lower in arm 1. Significantly fewer patients complained of anorexia or arthralgia in arm 1.

**8. Conclusions**

Kampo formulations may have efficacy for reducing the adverse effects of interferon therapy in patients with chronic hepatitis C.

**9. From Kampo medicine perspective**

Kojinmatsu was added in hope that its immunostimulatory activity would be coupled with the effects of keimakakuhanto (桂麻各半湯).

**10. Safety assessment in the article**

One patient in arm 1 discontinued treatment because of gastrointestinal symptoms on day 9 of Kampo formulation treatment and was excluded from further evaluation. Another patient complained of nausea/vomiting on day 9 of Kampo formulation treatment. Despite continuation of treatment, the symptoms disappeared after 5 days allowing further continuation of this patient's treatment.

**11. Abstractor's comments**

This paper describes an attempt to evaluate the efficacy of Kampo formulations against the adverse effects of interferon therapy in patients with chronic hepatitis C. The author's original formula was used and it is suggested that *happyozai* (発表剤, exterior-effusing formula) has certain efficacy for reducing influenza-like adverse effects of interferon. Unfortunately, the number of patients was very small, so future studies including a large number of patients are anticipated.

**12. Abstractor and date**

Oikawa T, 19 September 2008, 1 June 2010, 12 October 2012.