

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

Tanaka N, Matsuzaki Y, Osuga T, et al. A comparative study of IFN monotherapy versus IFN plus TJ-9 shosaikoto combination therapy in patients with chronic hepatitis C (interim report) . *Progress in Medicine* 1993; 13: 2868-72 (in Japanese).

1. Objectives

To evaluate the efficacy of interferon (IFN) plus shosaikoto (小柴胡湯) combination therapy for chronic hepatitis C.

2. Design

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

3. Setting

Three hospitals including Tsukuba University Hospital, Japan.

4. Participants

Thirty-six patients aged under 65 years with chronic hepatitis C.

5. Intervention

Arm 1: treatment with interferon-alpha (or -beta) 6 million units daily for 2 weeks, then 3 times weekly for 23 weeks + TSUMURA Shosaikoto (小柴胡湯) Extract Granules 2.5 g t.i.d. (n=15) for 1.5 year.
Arm 2: treatment with interferon alone for 23 weeks (n=21).

6. Main outcome measures

Alanine aminotransferase (ALT) level.

7. Main results

There was no significant difference in the time course of ALT levels between arms 1 and 2.

8. Conclusions

At the time of this interim report, the shosaikoto and IFN combination did not provide an enhanced therapeutic efficacy for chronic hepatitis C.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

None.

11. Abstractor's comments

This is an interim report on a clinical trial of interferon plus shosaikoto combination therapy for chronic hepatitis C, summarizing data from 36 patients who completed treatment, out of more than 100 patients who enrolled. Efficacy of this therapy was not demonstrated. But this is only an interim report and a final report is anticipated.

12. Abstractor and date

Oikawa T, 19 September 2008, 6 January 2010, 1 June 2010.