

13. Diseases of the Musculoskeletal System and Connective Tissue**Reference**

Wang XD, Yoshida K, Honda K, et al. Study of the immunoregulatory activity of the combination therapy with juzentaihoto and hachimijiogan in patients with disuse syndrome*. *Kampo Igaku (Kampo Medicine)* 2006; 30: 65-7 (in Japanese). Ichushi Web ID: 2006283912

1. Objectives

To evaluate the efficacy of juzentaihoto (十全大補湯) combined with hachimijiogan (八味地黄丸) in patients with disuse syndrome.

2. Design

Randomized controlled trial (envelope method) (RCT-envelope).

3. Setting

One community hospital, Japan.

4. Participants

Patients after a prolonged period of bed rest and tube feeding.

5. Intervention

Arm 1: Tsumura Juzentaihoto (十全大補湯) Extract Granules and Tsumura Hachimijiogan (八味地黄丸) Extract Granules 2.5 g b.i.d. each for 24 weeks, n=13.
Arm 2: No administration of Kampo drugs, n=15.

6. Main outcome measures

Laboratory tests: hemograms and urine tests performed at 0, 4, 8, 12, 16, 20, and 24 weeks. CD4 count, CD8 count, CD4/CD8 ratio, neutrophil phagocytotic activity, levels of immunoglobulins (IgM, IgG, and IgA) examined at 0, 12, and 24 weeks.

7. Main results

CD4/CD8 ratio and CD4 count were significantly increased in arm 1 compared to arm 2 at 12 weeks; however, no significant difference was observed at 24 weeks. There were no significant between-arm differences in the results of other tests.

8. Conclusions

In many cases, CD4/CD8 ratio and CD4 count are elevated at 12 weeks of administration.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Not documented.

11. Abstractor's comments

Immunoregulatory effect of the combination two Kampo drugs was assessed using lymphocyte surface markers CD4 and CD8. The finding of significant increases in CD4/CD8 ratio and CD4 count at 12 weeks, but not at 24 weeks, demands the conduct of further studies designed to reveal whether immune status was restored or regulated.

12. Abstractor and date

Namiki T, 12 March 2009, 1 June 2010.