

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

Watanabe A, Hasegawa S. Effect of combined Kampo medicines as adjuvant therapy for pulmonary tuberculosis. *Nippon Iji Shinpo (Japan Medical Journal)* 1992; (3553): 76-7 (in Japanese).

Watanabe A, Takahashi N, Uchida Y, et al. Efficacy of hochuekkito as adjuvant therapy for pulmonary tuberculosis. *JAMA (Japanese version)* 1992; 13 (6) suppl: 20-1 (in Japanese)

**1. Objectives**

To determine the effect of hochuekkito (補中益気湯) and shosaikoto (小柴胡湯) on improving appetite and host defense in patients undergoing chemotherapy for pulmonary tuberculosis.

**2. Design**

Randomized controlled trial (RCT).

**3. Setting**

One hospital, Japan.

**4. Participants**

One hundred and one hospitalized patients with sputum positive for tubercle bacilli and were treated with rifampicin, isoniazid, and streptomycin during a 5-year period from January 1987 to December 1991.

**5. Intervention**

Arm 1: chemotherapy alone (n=40).

Arm 2: chemotherapy + treatment with TSUMURA Hochuekkito (補中益気湯) Extract Granules 7.5 g/day (n=31).

Arm 3: chemotherapy + treatment with TSUMURA Hochuekkito (補中益気湯) Extract Granules 7.5 g/day and TSUMURA Shosaikoto (小柴胡湯) Extract Granules 7.5 g/day (n=30).

**6. Main outcome measures**

Body weight, degree of sputum smear positivity (on the Gaffky scale), erythrocyte sedimentation rate (ESR), and number of peripheral blood lymphocytes.

**7. Main results**

After admission, body weight began to increase 2 months after the start of the study treatment in all three arms. The gain was greater in arm 3 than in arm 1 at 3 months and greater in arms 2 and 3 than in arm 1 at 5 months. The weight gain [in kg] at 5 months in arms, 1, 2, and 3 was 3.2, 4.7, and 5.3, respectively. The number of peripheral blood lymphocytes was increased in all 3 arms during the course of treatment and there were no significant between-arm differences. In the subgroup with decreased number of peripheral blood lymphocytes on admission, weight gain was markedly greater in arms 2 and 3 than in arm 1. Furthermore, weight gain was more remarkable in elderly patients aged 60 or older (a total of 45 patients) who received Kampo medicine(s)-combined therapy than in all the patients, including younger patients, who received the combination.

**8. Conclusions**

Although they affected body weight and the number of peripheral blood lymphocytes but not ESR and sputum smear positivity, Kampo medicines are presumed to be a useful adjunct to antituberculosis therapy.

**9. From Kampo medicine perspective**

None.

**10. Safety assessment in the article**

Hepatic dysfunction occurred and treatment was discontinued in 2 patients of arm 1. In contrast, mild hepatic dysfunction occurred but treatment was continued in arms 2 and 3, indicating the possibility that Kampo medicines help prevent hepatic dysfunction.

**11. Abstractor's comments**

At the time when this comparative study was conducted, most tuberculosis patients who excreted bacilli had to be hospitalized for treatment. Recently, the number of tuberculosis patients has decreased and, thanks to early detection, most patients present mild disease. Yet some patients with severe disease still require long-term hospitalization. If the lifestyle characteristics of the patients and the severity of their disease had been clearly described, this paper would be helpful today. It is said that shosaikoto or something else was used as treatment for tuberculosis before the war. The both papers were published around the same time as the present paper. It included arms 1 and 2 of the present study and highlights the efficacy of hochuekkito.

**12. Abstractor and date**

Fujisawa M, 31 March 2009, 1 June 2010, 31 December 2013