

10. Respiratory Diseases (including Influenza and Rhinitis)**Reference**

Kaji M, Kashiwagi S, Yamakido M, et al. A double-blind, placebo-controlled study of TSUMURA Shosaikoto (TJ-9) for common cold*. *Rinsho to Kenkyu (Japanese Journal of Clinical and Experimental Study)* 2001; 78: 2252-68 (in Japanese). Ichushi Web ID: 2002145787 [MOL](#), [MOL-Lib](#)

1. Objectives

To assess the efficacy and safety of shosaikoto (小柴胡湯) in patients with common cold.

2. Design

Double-blind randomized controlled trial (DB-RCT)

3. Setting

From September 1995 until March 1999.

Ten university hospitals, 42 community and other hospitals, and 2 clinics, Japan.

4. Participants

Patients with persistent symptoms for more than 5 days after the onset of common cold, age from 25 to 75 years, and complaints of at least one of the following symptoms: oral discomfort (bitter taste, sticky sensation, dysgeusia), anorexia, or malaise.

5. Intervention

The placebo had similar appearance and properties. Concomitant drug use was basically prohibited, except for dimemorfan phosphate (Astomin tablets) after day 3.

Arm 1: TSUMURA Shosaikoto (小柴胡湯) Extract Granules (TJ-9) 2.5g t.i.d., n=131.

Arm 2: placebo 2.5 g t.i.d., n=119.

Duration of administration: 1 week or less

6. Main outcome measures

Global improvement rating (comprehensive evaluation based on improvement rating of each symptom and patient's impression), improvement rating of each symptom], and safety evaluation.

7. Main results

At baseline, the patients allotted to arm 1 were not matched to those allotted to arm 2 in the severity of headache, and the amount and viscosity of sputum. General improvement was significantly better in arm 1 than in arm 2, with the percentage of patients rated 4 (improved) or 5 (markedly improved) on a 5-point scale being 64.1% and 43.7% in arm 1 and arm 2, respectively. Individual symptoms (throat pain and malaise at day 3-4, clearance of sputum, appetite, joint pain and muscular pain at the end of study) all were significantly better in arm 1.

8. Conclusions

For patients with persistent common cold associated with oral discomfort (bitter taste, sticky sensation, dysgeusia), decreased appetite, and/or malaise, shosaikoto is effective and useful.

9. From Kampo medicine perspective

Subject selection was made on the basis of persistent symptoms and discomfort in the mouth, which indicate "shosaikoto-*sho*"

10. Safety assessment in the article

Ten (7.4%) of 136 subjects in arm 1 and 15 (11.4%) of 132 subjects in arm 2) experienced adverse effects. However, there were no serious adverse drug reactions.

11. Abstractor's comments

This study is a large-scale DB-RCT on Kampo therapy fitted to "*sho*" in Kampo medicine.

12. Abstractor and date

Fujisawa M, 15 June2007, 1 April 2008.