

**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.