

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

**Kato S, Matsuda T, Nakajima T, et al. Clinical significance of the combination therapy of smoking cessation and seihaito for chronic obstructive pulmonary disease. *Kampo to Saishin-chiryō (Kampo & the Newest Therapy)* 2005; 14: 260-5 (in Japanese). Ichushi Web ID: 2005292823**

Kato S, Oda K, Hasumi H, et al. The combined effect of smoking cessation and Seihai-to on airway clearance on COPD patients. *Kampo to Meneki-Arerugi (Kampo and Immuno-Allergy)* 2006; 19: 26-35 (in Japanese with English abstract).

**1. Objectives**

To assess the efficacy of smoking cessation combined with administration of seihaito (清肺湯) for chronic obstructive pulmonary disease (COPD).

**2. Design**

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

**3. Setting**

Two university hospitals, Japan.

**4. Participants**

Patients with GOLD stage 0, 1, or 2 COPD who had stopped smoking, but whose respiratory symptoms (cough, sputum, and dyspnea) were still present one month after smoking cessation, n=31.

**5. Intervention**

Arm 1: smoking cessation and administration of TSUMURA Seihaito (清肺湯) Extract Granules 9.0 g/day, for 24 months, n=16.

Arm 2: smoking cessation only, for 24 months, n=15.

**6. Main outcome measures**

Respiratory symptoms.

Chest radiography and chest CT findings (emphysema, organizing pneumonia, bronchial obstruction by sputum).

**7. Main results**

Respiratory symptoms were significantly improved in arm 1 compared with arm 2 for 1 to 6 months; however, no significant difference was found after 12 months. The imaging findings were significantly improved in arm 1 at 24 months. Diagnostic imaging showed significant improvement in organizing pneumonia and bronchial obstruction in arm 2 after 24 months and no improvement in emphysema in both arms.

**8. Conclusions**

Administration of seihaito for 6 months improves clinical symptoms, and administration for 24 months is necessary for improvement in imaging findings.

**9. From Kampo medicine perspective**

None.

**10. Safety assessment in the article**

Not documented.

**11. Abstractor's comments**

The information from this RCT included guidance on how to stop smoking using Kampo medicine as an add-on treatment. Dyspnea is a respiratory symptom that can be evaluated objectively by respiratory function testing and measurement of blood oxygen saturation. Future use of these tests in the follow-up period is desired. Future developments in this area of research hold promise.

**12. Abstractor and date**

Fujisawa M, 15 June 2007, 1 April 2008, 22 February 2009, 31 December 2013.