## 10. Respiratory Diseases (including Influenza and Rhinitis)

**References**

Ito S, Mikawa H. Effect of "TSUMURA Saiboku-to" (TJ-96) on bronchial asthma in children. *Kampo to Meneki-Arerugi* (*Kampo and Immuno-allergy*) 1990; 4: 115–25 (in Japanese with English abstract).
**Ito S, Mikawa H. Clinical evaluation of Saibokutou in the treatment of children with bronchial asthma. *Kiso to Rinsho* (*The Clinical Report*) 1992; 26: 3993–8 (in Japanese). Ichushi Web ID: 1993226668 MOL, MOL-Lib**

**1. Objectives**
To evaluate the efficacy and safety of saibokuto (柴朴湯) for the treatment cedar pollen allergy in children with bronchial asthma.

**2. Design**
Randomized controlled trial using sealed envelopes for allocation (RCT-envelope).

**3. Setting**
Two university hospitals (Department of Pediatrics, Faculty of Medicine, Kyoto University, and Kansai Medical University Rakusai Newtown Hospital) and six other hospitals, Japan.

**4. Participants**
Children with mild or moderate (symptoms of) bronchial asthma (n=43).

**5. Intervention**
Arm 1: TSUMURA Saibokuto (柴朴湯) Extract Granules 1.25 mg b.i.d. (for children less than 7 years old) or 2.5 g b.i.d. (for children 7 years or older) for 8–12 weeks (n=22).
Arm 2: tranilast 5 mg/kg/day in two or three divided doses for 4–12 weeks (n=21).

**6. Main outcome measures**
Frequency of asthma attacks (very frequent, moderately frequent, infrequent) in a week, and the severity score of the attack (severe=6, moderate=4, mild=1).

**7. Main results**
No severe attacks were observed in either arm after 5 weeks of treatment. Frequencies of moderate attacks were not significantly different between the two arms throughout the study period. Mild attack was less frequent in arm 2 than in arm 1. The frequency and severity scores were significantly decreased in arm 2 compared to arm 1 at 4–6 weeks of treatment ($P<0.05$), and significantly decreased in arm 1 compared to arm 2 at 11–12 weeks of treatment ($P<0.05$).

**8. Conclusions**
Saibokuto and tranilast have equivalent efficacy in children with mild to moderate bronchial asthma.

**9. From Kampo medicine perspective**
None.

**10. Safety assessment in the article**
No adverse effects were observed.

**11. Abstractor's comments**
Patient allocation by the envelope method makes the randomization process tenuous in this study. However, the value of this study is that it confirms the equivalent efficacy of saibokuto and tranilast as treatment for bronchial asthma in children. There is no placebo arm in this study. Use of a placebo arm may pose an ethical problem. Therefore, further randomized controlled clinical trials with cross-over design are indicated.

**12. Abstractor and date**
Okabe T, 19 August 2008, 1 June 2010, 31 December 2013.