#### **Evidence Reports of Kampo Treatment**

Task Force for Evidence Reports / Clinical Practice Guideline Committee for EBM, the Japan Society for Oriental Medicine

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

#### Reference

Tubaki T, Ebisawa M, Akimoto K, et al. Effects of Shinpi-to (*Shenbi-tang*) on bronchial asthma. *Kampo to Meneki-Arerugi (Kampo and Immuno-allergy)* 1994; 8: 65–71 (in Japanese with English abstract).

## 1. Objectives

To evaluate the effects of shinpito (神秘湯) on exercise-induced asthma and changes in clinical symptoms in patients with moderate to severe bronchial asthma.

# 2. Design

Randomized controlled trial (RCT).

# 3. Setting

One hospital, Japan.

# 4. Participants

Patients aged 7–15 years with moderate asthma (n=5) or severe asthma (n=7) who were treated concomitantly with the phylline, disodium cromoglycate, inhaled beclomethasone, and beta2-agonists. Patients were excluded who received oral steroids, had a predicted FEV1 of less than 80%, or had wheezing before exercise tests.

## 5. Intervention

The observation period was 2 weeks, and the administration period was 12 weeks.

The administered dose was one sachet b.i.d. to patients aged less than 13 years and one sachet t.i.d. to patients aged 13 or older.

Arm 1: administration of TSUMURA Shinpito (神秘湯) Extract Granules (n=7) (dose not described). Arm 2: EBIOS 1 g b.i.d. or t.i.d. (n=5).

## 6. Main outcome measures

Asthma symptom diary.

Respiratory function changes observed on ergometer exercise tests during the 2-week observation period and at the conclusion of shinpito administration.

# 7. Main results

In both arms, exercise lowered  $\text{FEV}_{1.0}$  below standard values after 5 minutes, and  $\text{FEV}_{1.0}$  gradually recovered. However, in arm 2 after administration of shinpito, the rate of this reduction was significantly inhibited immediately after and 5 minutes after exercise, and some inhibition was still observable 15, 30, and 60 minutes after exercise. In addition, a significant reduction in numbers of attacks was observed in arm 2, whereas no significant improvement was observe in arm 1.

## 8. Conclusions

Shinpito effectively improves the symptoms of bronchial asthma and reduces the number of exercise-induced asthma attacks.

- **9.** From Kampo medicine perspective None.
- **10.** Safety assessment in the article Not mentioned.

### **11.** Abstractor's comments

The result that shinpito is effective for exercise-induced asthma attacks is interesting. However, random grouping in this study seems unbalanced even after taking the severity into consideration: 5/7 subjects in arm 2 and 2/5 in arm 1 were treated with inhaled beclomethasone, while 3/7 subjects in arm 2 and 0/5 in arm 1 were treated with beta2-agonists. Further studies with more patients are expected.

### **12.** Abstractor and date

Fujisawa M, 13 October 2008, 1 June 2010, 31 December 2013.