

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

Nishizawa Y, Nishizawa Y, Goto GH, et al. A randomized, group-parallel comparative trial of the suppressive effect of Chinese traditional medicine, shen-mi-tang (shin-pi-to), compared to sodium cromoglycate inhalation in improving subjective and objective symptoms in bronchial asthmatics. *Jibi-inkoka Tenbo (Oto-rhino-laryngology Tokyo)* 2004; 47: 20-7 (in Japanese with English abstract).  
CENTRAL ID: CN-00496741, Ichushi Web ID: 2005016956

**1. Objectives**

To assess the efficacy and safety of inhaled shimpito (神秘湯) therapy for improving asthma symptoms in patients with aspirin-induced asthma.

**2. Design**

Randomized controlled trial (RCT).

**3. Setting**

Several clinics and other health care facilities, Osaka prefecture, Japan.

**4. Participants**

Patients with aspirin-induced asthma, whose thresholds for induction of asthma (attacks) have been determined, n=161.

**5. Intervention**

Arm 1: inhalation of shimpito (神秘湯), 500 µg in four divided doses, n=81.

Arm 2: inhalation of cromoglycate, 5 mg q.i.d., n=80.

Duration of the study was 3 years.

**6. Main outcome measures**

1) Frequency of asthma attacks (or exacerbations), 2) improvement in health-related QOL, 3) improvement in chronic pain, 4) leukotriene level in bronchoalveolar lavage (BAL) fluid

**7. Main results**

In arm 1, frequency of asthma attacks and leukotriene level in BAL fluid were significantly reduced, and QOL and chronic pain were significantly improved when compared with arm 2.

**8. Conclusions**

Inhaled shimpito therapy suppresses production of leukotrienes, prevents exacerbation of aspirin-induced asthma, alleviated chronic pain, and improved QOL.

**9. From Kampo medicine perspective**

None.

**10. Safety assessment in the article**

Fewer cases and subjects had abnormal laboratory findings and adverse reactions in arm 1 than in arm 2.

**11. Abstractor's comments**

The authors do not specify the medical facilities where this clinical trial (described as multicenter trial) actually took place. In this prospective, randomized study, the number of withdrawals and cases analyzed during the 3-year period of observation for 161 enrolled subjects is not stated. It is unclear whether there were any withdrawals during this period. Aspirin-induced asthma comprises 4-10% of all cases of asthma. Inhaled corticosteroids are the most common medications used for asthma therapy. This study implies that inhaled shimpito therapy is more efficacious in the management of asthma than inhaled cromoglycate therapy. In patients with aspirin-induced asthma, health-related QOL is generally not good because of limitation on the use of nonsteroidal anti-inflammatory drugs (NSAIDs) for pain and inflammation. However, shimpito can improve these symptoms. Further studies are awaited to assess whether oral administration of shimpito also has similar efficacy when used in subjects with the appropriate "sho."

**12. Abstractor and date**

Okabe T, 15 June 2007, 1 April 2008, 1 June 2010.