

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

Nishizawa Y, Nishizawa Y, Yoshioka F, et al. Suppressive effect of Chinese traditional medicine, she-bi-tang (shinpi to) on bronchospasm in aspirin-intolerant bronchial asthmatic patients – a randomized, group-paralleled comparative trial –. *Jibi-inkoka Tenbo (Oto-rhino-laryngology Tokyo)* 2003; 46: 3-14 (in Japanese). CENTRAL ID: CN-00451669, Ichushi Web ID: 2004041278

1. Objectives

To assess the efficacy and safety of inhaled shimpito (神秘湯) for the control of aspirin-induced asthma.

2. Design

Randomized controlled trial (RCT).

3. Setting

Several clinics and others, Osaka prefecture, Japan.

4. Participants

Patients with histories of aspirin-induced asthma, whose threshold levels of inhaled lysine-aspirin are determined, n=114.

5. Intervention

Arm 1: inhalation of TSUMURA Shimpito (神秘湯) Extract Granules, 500 µg in four divided doses, n=53.
Arm 2: inhalation of cromoglycate, 5 mg q.i.d., n=61.
Duration of the study was 1 year.

6. Main outcome measures

The effect was evaluated by assessing 1) leukotrienes levels in bronchoalveolar lavage (BAL) fluid, 2) forced expiratory volume in 1 second (FEV_{1.0}) after lysine-aspirin inhalation, and 3) frequency of asthma attacks (or exacerbations).

7. Main results

The decrease in FEV_{1.0} after lysine-aspirin inhalation was significantly greater in arm 1 than arm 2. Also, the frequency of asthma attacks and leukotriene levels in BAL fluid were decreased in arm 1 relative to arm 2.

8. Conclusions

Inhaled shimpito is more efficacious than inhaled cromoglycate for the management of aspirin-induced asthma.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

The frequency of both abnormal laboratory findings and adverse reactions were higher in arm 2 than in arm 1 (number of cases are unclear because the results were omitted in this paper).

11. Abstractor's comments

Despite the term “multicenter, randomized” in the title, the method of randomization is not described, and the facilities where this clinical trial was actually performed (not the research institute) are unspecified. This paper does not state the number of withdrawals and analyzed cases during the 1-year follow-up of 114 subjects. Might it mean no withdrawals during the 1-year treatment period? Aspirin-induced asthma comprises 4-10% of all asthma cases. Inhaled corticosteroids are the most commonly used asthma medications. This study implies the greater efficacy of inhaled shimpito therapy in the management of asthma when compared with that of inhaled cromoglycate therapy. Further studies are awaited to assess whether oral administration of shimpito also provides similar efficacy when used by subjects with the appropriate “*sho*.”

12. Abstractor and date

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