

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

Nishizawa Y, Nishizawa Y, Yoshioka F, et al. Suppressive effect of Japanese herbal medicine, saiboku-to (cai-pu-tang) on bronchospasms in aspirin-induced bronchial asthmatic patients. A randomized, double-blind test. *Jibi-inkoka Tenbo (Oto-Rhino-Laryngology Tokyo)* 2001; 44: 5-13 (in Japanese with English abstract). Ichushi Web ID: 2002025794

1. Objectives

Development of saibokuto (柴朴湯) inhalation therapy, and to evaluate its efficacy in preventing attacks of aspirin-induced asthma.

2. Design

Double-blind, randomized controlled trial (DB-RCT).

3. Setting

Two clinics, Japan.

4. Participants

Patients with aspirin-induced asthma in whom the threshold dose of L-lysine-aspirin for provoking an asthma attack was determined by inhalation, n=74.

5. Intervention

Saibokuto inhalant: TSUMURA Saibokuto (柴朴湯) Extract Granules (TJ-96) were dissolved in injectable saline, sonicated for 90 minutes, and filtered through a Millipore sterile 0.22-micron filter. After adjustment to a concentration of 100 µg/mL, 5 mL of the inhalant was inhaled three times a day.

Arm 1: inhalation of saibokuto (柴朴湯) inhalant for 6 months, n=35.

Arm 2: inhalation of saline for 6 months, n=39.

6. Main outcome measures

The efficacy and safety of inhaled saibokuto for reducing the frequency of asthma attacks.

7. Main results

Saibokuto inhalant was newly developed. Prolonged inhalant usage significantly reduced the frequency of asthma attacks (0.004 times/person/6 months in arm 1 vs 0.120 times/person/6 months in arm 2).

8. Conclusions

Inhalation, compared with oral administration, can increase the concentration of saibokuto in the lung to the same level as achieved in experiments *in vivo* and *in vitro*, resulting in suppression of the production and release of biologically active substances in bronchoalveolar lavage fluid, and thereby of asthma attacks.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Adverse effects were observed in 7 cases (20.0%) in arm 1 and 7 cases (17.9%) in arm 2, none of which led to withdrawal from the study.

11. Abstractor's comments

The preparation of saibokuto inhalant (as described above) involved more than simply dissolving the extract granules in saline.

12. Abstractor and date

Fujisawa M, 15 June 2007, 1 April 2008, 1 June 2010, 31 December 2013.