Evidence Reports of Kampo Treatment

Task Force for Evidence Reports, the Japan Society for Oriental Medicine
Note) The quality of this RCT has not been validated by the EBM committee of the Japan Society for Oriental Medicine.

10. Respiratory Diseases (including Influenza and Rhinitis)

Reference

Itagaki K, Efficacy of shimpito for treatment of cough associated with cold syndrome.* *Igaku to Yakugaku* (*Japanese Journal of Medicine and Pharmaceutical Science*) 2013; 70: 813-6 (in Japanese). Ichushi Web ID: 2014063683 MOL, MOL-Lib

1. Objectives

To evaluate the efficacy and safety of shimpito (神秘湯) for treatment of cough associated with cold syndrome.

2. Design

Quasi-randomized controlled trial (quasi-RCT).

3. Setting

One clinic, Japan.

4. Participants

Sixteen patients (3 males and 13 females) who visited the clinic between January 2011 and May 2011 and had a diagnosis of cold syndrome with severe or persistent cough.

5. Intervention

Arm 1: Kracie Shimpito (神秘湯) Extract Granules administered orally at 3.0 g b.i.d. before or between meals for 7 days and lysozyme hydrochloride 90 mg t.i.d. + carbocysteine 500 mg t.i.d. after meals for 7 days (n=9).

Arm 2: Lysozyme hydrochloride 90 mg t.i.d. + carbocysteine 500 mg t.i.d. after meals for 7 days (n=7).

6. Main outcome measures

The severity of cough was assessed on the following 4-point scale: 0, none; 1, mild; 2, moderate; 3, severe. Subjects recorded the severity scores in a cough diary. The scores on each day were compared to those on Day 1 using the Wilcoxon signed-rank test.

7. Main results

The scores improved significantly after Day 4 (P<0.05) in Arm 1 and after Day 6 in Arm 2 (P<0.05).

8. Conclusions

Shimpito is effective for the treatment of refractory cough associated with cold syndrome.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

No adverse events were noted.

11. Abstractor's comments

This is a meaningful clinical study because the author, a physician at the study site, conducted the study, in the midst of daily busy clinical practice, to evaluate the efficacy of a Kampo medicine in patients with cough due to cold, which is a common symptoms. However, since some subjects with persistent cough were assigned to the control arm, the inter-arm difference in the period from onset to the start of the study investigation was large: 4.7 ± 1.7 days in the shimpito arm and 16.7 ± 18.4 days in the control arm. Persistent cough might be refractory and affect the results of the study. In addition, intra-arm (but not inter-arm) cough severity scores were compared; therefore, the efficacy of shimpito compared with that of control drugs remains unknown. Since it is very important to make a continuous effort to elucidate the efficacy of Kampo medicine against common symptoms in daily clinical settings, a larger number of such clinical studies are anticipated..

12. Abstractor and date

Fujisawa M, 31 March 2017; Goto H, 31 March 2017.