10. Respiratory Diseases (including Influenza and Rhinitis)

Reference

Baba S, Takasaka T, Inamura N, et al. Double-blind clinical trial of Sho-seiryu-to (TJ-19) for perennial nasal allergy. *Jibiinkoka Rinsho* (*Practica otologica*) 1995; 88: 389–405 (in Japanese with English abstract). CENTRAL ID: CN-00192055, Ichushi Web ID: 1995184251

1. Objectives

To evaluate the efficacy and safety of shoseiryuto (小青竜湯) for perennial nasal allergy.

2. Design

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

3. Setting

Twenty-six university hospitals and 35 other hospitals, Japan.

4. Participants

Patients with perennial nasal allergy who visited otolaryngologists in 61 hospitals in the 8-month period from June 1993 to January 1994 (n=220).

5. Intervention

The package and appearance of the placebo were indistinguishable from those of shoseiryuto.
Duration of administration was 2 weeks. On-demand use of clemastine fumarate was permitted in case the symptoms were severe.
Arm 1: TSUMURA Shoseiryuto (小青竜湯) Extract Granules, 3.0 g t.i.d. (n=110).
Arm 2: placebo 3.0 g t.i.d. (n=110).

6. Main outcome measures

Overall general improvement, improvements in each symptom, safety, and the relationship between body-constitution and efficacy.

7. Main results

The number of subjects analyzed was 186 for overall general improvement, 217 for general safety, and 189 for usefulness. In arm 1, general improvement was high in 12.0% of the patients and moderate in 32.6%, and was significantly greater than in arm 2 (5.3% and 12.8%, respectively). Patients in arm 1 had significantly greater improvement in sneezing, nasal discharge, and nasal obstruction.
The efficacy of shoseiryuto was significantly higher in those with “average” or “muscular and strongly built” body type, “average to pale” facial color, “average” voice, “neither hot nor cold” or “sensitive to heat” cold or hot constitution, “warm” or “average” hands and feet, and “excess” or “average” sweating, as determined from questionnaire responses.

8. Conclusions

Shoseiryuto has significantly better efficacy (overall general improvement, improvements in each symptom, and usefulness).

9. From Kampo medicine perspective

The targets of shoseiryuto are watery and foamy phlegm, watery nasal discharge, and sneezing, in other words, the symptoms of allergic rhinitis.

10. Safety assessment in the article

Adverse reactions possibly related to the administered drug were observed in 6.4% of the placebo group and 6.5% of the shoseiryuto group. Patients treated with shoseiryuto had mild symptoms (digestive symptoms, headache, and facial edema), and one patient had mild elevations in GOT and GPT, neither of which led to the discontinuance of administration.

11. Abstractor’s comments

This is a full-scale, nationwide, and large RCT.

12. Abstractor and date

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