10. Respiratory Diseases (including Influenza and Rhinitis)

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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**