

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

Sakurada T, Ikeda K, Takasaka T, et al. Clinical effectiveness of Kampo medicine for chronic rhinitis and sinusitis. *Jibiinkoka Rinsho (Practica otologica)* 1992;85:1341–6 (in Japanese with English abstract).

1. Objectives

To determine the effectiveness of Kampo medicines for chronic rhinitis and sinusitis.

2. Design

Randomized controlled trial using sealed envelopes for allocation (RCT-envelope).

3. Setting

One university and 5 hospitals, Japan.

4. Participants

Six patients with non-allergic chronic rhinitis and 61 with chronic sinusitis who first visited the participating institutions between November 1989 and June 1990.

5. Intervention

Arm 1: oral administration of TSUMURA Shin'iseihaito (辛夷清肺湯) Extract Granules 2.5 g t.i.d. before meals for 4-8 weeks (n=39).

Arm 2: oral treatment with TSUMURA Shigyakusan (四逆散) Extract Granules 2.5 g t.i.d. before meals for 4-8 weeks (n=28).

6. Main outcome measures

Severity of subjective symptoms: rhinorrhea, ease of nose blowing, postnasal drip, nasal obstruction, heaviness of head (headache), and olfactory disturbance.

Objective findings: redness and edema of the nasal mucosa, characteristics of nasal discharge.

Examinations: neutrophil count in nasal discharge, rhinomanometry.

7. Main results

Improvement in subjective symptoms was at least mild in 76.3% and 59.3% of patients in arms 1 and 2, respectively; the between-arm difference was not significant. Improvements in objective findings were not significantly different between arm 1 (60.5%) and arm 2 (70.4%). There were no significant between-arm differences in neutrophil count, nasal discharge, and rhinomanometric results.

8. Conclusions

The preceding paper was Ikeda K, Takasaka T, Kusakari J, et al. Outcome of treatment with Leftose (lysozyme hydrochloride) for chronic sinusitis – a comparison of clinical efficacy in adults versus children -. *Jibiinkoka Rinsho (Practica otologica)* 1984;77:1863–69. The present study revealed that Kampo medicines had efficacy comparable with that of Leftose (i.e., mild or greater improvement in 63% of patients with chronic sinusitis).

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

One shin'iseihaito-treated patient had chest distress, which was considered unlikely to be related to the drug.

11. Abstractor's comments

In the treatment of chronic sinusitis, long-term low-dose administration of 14-membered ring macrolide antibiotics became available around 1990 and now these antibiotics are used as standard conservative therapy. Anti-inflammatory enzymes, including Leftose, were commonly used before 1990 and otology physicians reported reasonably adequate efficacy of these drugs. Now they are combined with these antibiotics to relieve symptoms.

12. Abstractor and date

Fujisawa M, 1 June 2009, 1 June 2010.