10. Respiratory Diseases (including Influenza and Rhinitis)

Reference

Nakai Y, Ohashi Y, Esaki Y, et al. Clinical evaluation of maobushisaishinto for nasal allergy*. *Jibi-inkouka Tenbou* (*Oto-Rhino-Laryngology*, Tokyo) 1990; 33: 655–73 (in Japanese).

1. Objectives

To evaluate the efficacy and safety of maobushisaishinto (麻黄附子細辛湯) extract granules prepared based on *Shanghanlun* (傷寒論, *Treatise on Cold Damage Diseases*) and conventionally-prepared maobushisaishinto extract powder in the treatment of perennial nasal allergy.

2. Design

Quasi-randomized controlled trial (quasi-RCT), Japan.

3. Setting

Departments of otorhinolaryngology of 5 university hospitals and 10 general hospitals (including Osaka City University Hospital, Teikyo University Mizonokuchi Hospital, and Nagoya City University Hospital).

4. Participants

One hundred and fifty-five patients with moderate or severe perennial nasal allergy.

5. Intervention

Arm 1: oral treatment with Kotaro Maobushisaishinto (麻黄附子細辛湯) Extract Fine Granules (content of currently-available capsule formulation) 1 g t.i.d. for 4 weeks (n=74).

Arm 2: oral treatment with Kotaro Maobushisaishinto (麻黄附子細辛湯) Extract Powder (old product: currently not available) 2 g t.i.d. for 4 weeks (n=81).

6. Main outcome measures

Nasal symptoms (paroxysmal sneezing, nasal discharge, nasal congestion, olfactory disturbance, interference with activities of daily living), rhinoscopic findings, severity, and nasal allergy tests (skin reaction, nasal provocation test, eosinophil count in nasal discharge).

7. Main results

Efficacy analyses revealed marked or moderate response in 28 out of 52 patients (53.8%) included in arm 1 and 27 out of 59 (45.8%) included in arm 2 at 2 weeks, and in 33 of 44 (76.7%) in arm 1 and 33 of 52 (63.5%) in arm 2 at 4 weeks; there was no between-arm difference at both time points.

8. Conclusions

The efficacy of maobushisaishinto extract powder prepared by the conventional method for perennial nasal allergy is comparable to that of maobushisaishinto extract fine granules prepared on the basis of *Shanghanlun*.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

In patients who received maobushisaishinto extract powder, 4 (6.15%) experienced adverse reactions: gastrointestinal symptoms in 3 (stomach ache, anorexia, nausea, and dysgeusia) and sleepiness in 1. In patients who received maobushisaishinto extract fine granules, 3 (5.17%) experienced adverse reactions: gastrointestinal symptoms in 2 (gastric distress, dry mouth) and headache/heaviness of the head in 1.

11. Abstractor's comments

It is noteworthy that this multicenter controlled clinical trial demonstrated equivalent efficacy of two different maobushisaishinto formulations for perennial nasal allergy. Outcomes were assessed using not only subjective symptoms but also objective measures (such as rhinoscopic findings) and the results are highly reliable. Unfortunately, the randomization in this study seems to be flawed. A randomized controlled trial including placebo and an active reference is desired.

12. Abstractor and date

Okabe T, 18 August 2008, 1 June 2010, 31 December 2013.