

13. Diseases of the Musculoskeletal System and Connective Tissue**Reference**

Nishizawa Y, Nishizawa Y, Yoshioka F, et al. Improving effect of Chinese herb medicine mai-men-dong-tang (Japanese name: bakumondo-to) comparative with sicca syndrome in especial salivary patients with secondary Sjögren's syndrome in multicenter, well controlled, long-term comparative study. *Nihon Daekisen Gakkaishi (Journal of the Japan Salivary Gland Society)* 2003; 44: 65-70.

1. Objectives

To evaluate the efficacy and safety of bakumondoto (麦門冬湯) for treatment of dryness associated with secondary Sjögren's syndrome.

2. Design

Randomized controlled trial (RCT).

3. Setting

Not mentioned, Japan.

4. Participants

Seven-hundred and fifty-six patients with secondary Sjögren's syndrome.

5. Intervention

Arm 1: bakumondoto (麦門冬湯) extract granules 3 g t.i.d. for 1 year (n=380).

Arm 2: bromhexine hydrochloride 4 g t.i.d. for 1 year (n=374).

6. Main outcome measures

Dryness, amounts of salivation/lacrimation, joint pain, amount of sputum, Raynaud's symptom.

7. Main results

The amount of salivation was increased in both arms, but it was significantly higher in the bakumondoto group. The amount of lacrimation was significantly increased only in the bakumondoto group. The following outcome measures were also improved only in the bakumondoto group: dryness, Raynaud's symptom, joint pain, and cough/amount of sputum. The inflammatory reaction remained unchanged in both groups.

8. Conclusions

Bakumondoto is more effective and safer than bromhexine hydrochloride and therefore useful for treating dryness associated with secondary Sjögren's syndrome.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

There were fewer adverse drug reactions (ADRs) or laboratory abnormalities in the bakumondoto group than in the bromhexine hydrochloride group (the number of ADRs not indicated).

11. Abstractor's comments

This study provides objective evidence for the efficacy of bakumondoto for treating dryness associated with secondary Sjögren's syndrome. The duration and dosage of bakumondoto treatment was correlated with the amount of salivation, suggesting a dose-dependent effect.

12. Abstractor and date

Kogure T, 15 June 2007, 1 April 2008.