

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

Nishizawa Y, Nishizawa Y, Yoshioka F, et al. Long-term effect of traditional Chinese herbal medicine, mai-men-don-tang on sicca syndrome, especially, salivary secretion in patients with primary Sjögren's syndrome: a multicenter, randomized well controlled group-parallel double-blinded study. *Nihon Daekisen Gakkaishi (Journal of the Japan Salivary Gland Society)* 2004; 45: 66-74.

1. Objectives

To evaluate the efficacy and safety of bakumondoto (麦門冬湯) therapy for salivary hyposalivation associated with primary Sjögren's syndrome.

2. Design

Double-blind, randomized controlled trial (RCT).

3. Setting

Two clinics, three university hospitals, and one general hospital, Japan.

4. Participants

Two-hundred and twenty-nine patients with primary Sjögren's syndrome.

5. Intervention

Arm 1: bakumondoto (麦門冬湯) extract granules 3 g t.i.d. before meals for 6 months (n=115).
Arm 2: placebo 3 g t.i.d. before meals for 6 months (n=114).

6. Main outcome measures

Dryness, amounts of salivation/lacrimation, joint pain, amount of sputum, Raynaud's symptom, limb skin temperature, and inflammatory reaction.

7. Main results

Salivation was increased in the bakumondoto group but decreased in the placebo group. Subjective symptoms were improved in the bakumondoto group but remained unchanged or were aggravated in the placebo group. Inflammatory reaction improved significantly only in the bakumondoto group.

8. Conclusions

Bakumondoto is effective and safe for the relief of subjective symptoms and salivary hyposalivation associated with primary 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 or fewer patients with ADRs or laboratory abnormalities in the bakumondoto group than in the bromhexine hydrochloride group. There were no serious ADRs or laboratory abnormalities leading to treatment discontinuation in either group (the number of events not specified).

11. Abstractor's comments

This study provides objective evidence for the efficacy of bakumondoto in the treatment of dryness associated with primary Sjögren's syndrome.

12. Abstractor and date

Kogure T, 15 June 2007, 1 April 2008, 31 December 2013.