

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

Nishizawa Y, Nishizawa Y, Goto GH, et al. The multicenter randomized comparative study of Kampo herbal medicine, mai-men-dong-tang (Japanese name bakumondo-to) compared with bromhexine on salivary secretion in secondary Sjögren's syndrome. *Itami to Kampo (Pain and Kampo Medicine)* 2004; 14: 10-7 (in Japanese with English abstract). Ichushi Web ID: 2006260917

1. Objectives

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

2. Design

Randomized controlled trial (RCT).

3. Setting

Three clinics and 3 university hospitals, Japan.

4. Participants

Eight-hundred and forty-seven patients with secondary Sjögren's syndrome.

5. Intervention

Arm 1: bakumondoto (麦門冬湯) extract granules 3 g t.i.d. before meals for 1 year (n=424).

Arm 2: bromhexine hydrochloride 4 g t.i.d. before meals for 1 year (n=423).

6. Main outcome measures

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

7. Main results

The amount of salivation was increased in both arms but was significantly higher in the bakumondoto group. Among bakumondoto-treated patients, those with mild disease showed significantly larger increases, whereas those with severe disease showed larger percent increases. The amount of lacrimation was significantly increased only in the bakumondoto group. Only in the bakumondoto group, the following variables were also improved: dryness, Raynaud's symptom, joint pain, cough/amount of sputum, and lowered temperature of the limb skin.

8. Conclusions

Bakumondoto is more effective and safer than bromhexine hydrochloride and therefore beneficial for treatment of mouth 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 the treatment of dryness associated with secondary Sjögren's syndrome. In the text, the dose of bromhexine hydrochloride was indicated as 120 mg, instead of the correct dose of 12 mg.

This paper seems to include data from the preliminary clinical trial published in *Nihon Daekisen Gakkaishi (Journal of the Japan Salivary Gland Society)* 2003; 44: 65-70.

12. Abstractor and date

Kogure T, 15 June 2007, 1 April 2008.