

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

Nishizawa Y, Nishizawa Y, Yoshioka F, et al. Long-term effects of traditional Chinese herbal medicine, mai-men-dong-tang (Japanese name: bakumondo-to) compared with bromhexine, hydrochloride on sicca syndrome, especially, salivary secretion in patients with primary Sjögren's syndrome: a multicenter, randomized well controlled group parallel comparative trial study with bromhexine. *Nihon Daekisen Gakkaishi (Journal of the Japan Salivary Gland Society)* 2002; 43: 62-6. Ichushi Web ID: 2005101735

1. Objectives

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

2. Design

Randomized controlled trial (RCT).

3. Setting

Not mentioned, Japan.

4. Participants

One-hundred and six patients with primary Sjögren's syndrome.

5. Intervention

Arm 1: bakumondoto (麦門冬湯) extract granules 3 g t.i.d. for 1 year. (n=51)

Arm 2: bromhexine hydrochloride 4 g t.i.d. for 1 year. (n=54)

6. Main outcome measures

Dryness, amount of salivation/lacrimation, and inflammatory reaction.

7. Main results

Salivation was increased in both groups but was significantly increased in the bakumondoto group. Lacrimation was significantly increased only in the bakumondoto group. Dryness was also improved only in the bakumondoto group. The inflammatory reaction remained unchanged in both groups.

8. Conclusions

Bakumondoto is more effective than bromhexine hydrochloride and safe in the treatment of dryness 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 in the bakumondoto group than in the bromhexine hydrochloride group (the number of ADRs not specified).

11. Abstractor's comments

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

12. Abstractor and date

Kogure T, 15 June 2007, 1 April 2008, 12 October 2011.