

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

Ohno S. The effect of Kampo medicine on salivary secretion in Sjögren's syndrome. *Kampo to Saishin-chiryō (Kampo & the Newest Therapy)* 2006; 15: 134-40 (in Japanese). Ichushi Web ID: 2006203175

1. Objectives

To evaluate the efficacy for Sjögren's syndrome.

2. Design

Quasi-randomized controlled trial (quasi-RCT).

3. Setting

Outpatient Department of Rheumatology, Samitama Medical University Hospital, Japan.

4. Participants

Sixty-four patients with Sjögren's syndrome.

5. Intervention

Arm 1: 4-week administration of Kampo medicine extracts that affect salivary secretion (3 g t.i.d. of TSUMURA Bakumondoto (麦門冬湯) Extract Granules alone [n=23]; 3 g t.i.d. of TSUMURA Bakumondoto (麦門冬湯) Extract Granules + 2.5 g t.i.d. of TSUMURA Rokumigan (六味丸) Extract Granules [n=3]; 3 g t.i.d. of TSUMURA Bakumondoto (麦門冬湯) Extract Granules + 2.5 g t.i.d. of TSUMURA Hachimijiogan (八味地黄丸) Extract Granules [n=4]) according to *sho* (証, pattern) (n=32; after 2 dropped out, 30 included for analysis).

Arm 2: 4-week administration of 2.5 g t.i.d. of TSUMURA Hochuekkito (補中益氣湯) Extract Granules (n=32; after 4 dropped out, 28 included for analysis).

6. Main outcome measures

Change in salivary secretion from pre- to post-administration, measured using a chewing gum test.

7. Main results

Twenty-seven out of 30 patients in arm 1 demonstrated increase in salivary secretion, with a significant increase in mean pre-treatment secretion of 8.2±1.2 mL to post-treatment average of 12.0±1.4 mL ($P<0.005$). There was no statistical significance between pre- and post-treatment secretions in arm 2. The amount of increase in salivary secretions before and after the treatment in arm 1 was significantly greater than arm 2 ($P<0.005$).

8. Conclusions

A Kampo medicine with moisturizing effect (but not a medicine without this effect) increases the amount of salivary secretion.

9. From Kampo medicine perspective

Arm 1 used "bensho (弁証)" (Kampo diagnosis) to allocate patients, specifically "jinkyo" (腎虚, kidney deficiency) which included 3 or more of the following 6 symptoms: 1) heaviness of the back; 2) heaviness in the lower legs with pain in heels and lateral surface of the lower legs; 3) tinnitus/hearing loss; 4) loss of hair and hair luster; 5) looseness or loss of teeth; and 6) sexual dysfunction (impotence, nocturnal emission). Kampo formulations for Arm 1 were selected based on the status of jinkyo: 1) bakumondoto alone for negative jinkyo; 2) bakumondoto plus rokumigan for jinkyo without chills; and 3) bakumondoto plus hachimijiogan for jinkyo with chills.

10. Safety assessment in the article

Not mentioned.

11. Abstractor's comments

This is an interesting quasi-randomized controlled trial that is plausible for its attempt in incorporating "sho" (証) diagnosis for selection of treatment. Results from the trial demonstrated that bakumondoto, moisturizing formula, with other Kampo formulations combination effectively enhanced salivary secretion in patients with Sjögren's syndrome than hochuekkito which was used as a control. A total of three pattern of combinations of Kampo formulation(s) were established for arm 1 based on various manifestations of jinkyo. 23 out of 30 patients (77%) in arm 1 received bakumondoto only. Future studies with improved RCT design and comparison with placebo or Western drug as a control appear warranted.

12. Abstractor and date

Namiki T, 17 March 2009, 1 June 2010, 31 December 2013.