

14. Genitourinary Tract Disorders (including Climacteric Disorders)**Reference**

Inoue M. Kampo treatment for mastitis - kamishoyosan - *. *Kampo Igaku (Kampo Medicine)* 1994; 18: 238–41 (in Japanese).

1. Objectives

To evaluate the efficacy of kamishoyosan (加味逍遙散) in the treatment of mastitis.

2. Design

Randomized controlled trial using sealed envelopes for allocation (RCT-envelope).

3. Setting

Outpatient Department of Breast, Japanese Red Cross Medical Center, Japan.

4. Participants

Two-hundred and eighty-one patients diagnosed with mastopathy based on findings of breast imaging, ultrasonography, and mammography.

5. Intervention

Arm 1: TSUMURA Kamishoyosan (加味逍遙散) Extract Granules 2.5 g t.i.d. for 4 weeks (n=169).

Arm 2: TSUMURA Keishibukuryogan (桂枝茯苓丸群) Extract Granules 2.5 g t.i.d. for 4 weeks (n=39).

6. Main outcome measures

Patients were classified into *jitsusho* (実証, excess pattern), *chukansho* (中間証, intermediate pattern), or *kyosho* (虚証, deficiency pattern) based on appetite, bowel movements, sensitivity to heat or cold, presence or absence of feeling cold, menstruation, use of hormones, tongue diagnosis, abdominal examination, etc. In patients with each *sho* (証, pattern), efficacy for breast pain, mammary gland swelling, symptoms of mastopathy, was judged from patient complaints.

7. Main results

Kamishoyosan and keishibukuryogan had similar efficacies.

8. Conclusions

Since *kuoketsuzai* (駆才血劑, blood stasis-expelling formulae) such as keishibukuryogan and tokakujokito are indicated for *jitsusho* (実証, excess pattern), kamishoyosan will provide another therapeutic option.

9. From Kampo medicine perspective

Mastopathy is frequently treated with *kuoketsuzai* (駆才血劑, blood stasis-expelling formulae); however, since its symptoms overlap with those of *kanqiukketsu* (肝気鬱結, liver *qi* depression) including breast pain, kamishoyosan, a saiko-agent (柴胡劑), would also be important.

10. Safety assessment in the article

There were no adverse events.

11. Abstractor's comments

This paper argues that while keishibukuryogan is used for *jitsusho* (実証, excess pattern), formulae for *chukansho* (中間証, intermediate pattern) or *kyosho* (虚証, deficiency pattern) such as kamishoyosan are necessary. This trial is meaningful because it was designed from such a viewpoint. This argument is verifiable, only if patients with *kyosho* (虚証, deficiency pattern) are allocated to and do not respond to treatment with keishibukuryogan (used as control). Regrettably, however, the allocation of patients at a ratio of 3:1 to kamishoyosan and keishibukuryogan in this trial resulted in a keishibukuryogan group without patients with *kyosho* (虚証, deficiency pattern), making it impossible to justify the author's argument. A similar trial demonstrating the usefulness of kamishoyosan in patients with *kyosho* (虚証, deficiency pattern) is awaited.

12. Abstractor and date

Nakata H, 10 January 2009, 1 June 2010, 31 December 2013.