

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

Inoue M. Kampo therapy for mastitis - shigyakusan - . *Kampo Igaku (Kampo Medicine)* 1990; 14: 132–6.

1. Objectives

To evaluate the efficacy of shigyakusan (四逆散) 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 twenty patients diagnosed with mastopathy based on findings of breast imaging, ultrasonography, and mammography between July 1988 and June 1989.

5. Intervention

Arm 1: shigyakusan (四逆散) group, TSUMURA Shigyakusan (四逆散) Extract Granules 2.5 g t.i.d. (n=111).

Arm 2: keishibukuryogan (桂枝茯苓丸) group, TSUMURA Keishibukuryogan (桂枝茯苓丸群) Extract Granules 2.5 g t.i.d. (n=41).

Patients were allocated to arm 1 and arm 2 at a ratio of 3:1.

Patients with symptoms completely resolved when primary efficacy was evaluated at 4 weeks completed treatment. Patients showing a tendency for improvement were given the same prescription for additional 4 weeks. Patients showing no tendency for improvement underwent fine-needle aspiration biopsy to eliminate the possibility of malignancy, received keishibukuryogan (桂枝茯苓丸) when they were in arm 1 and shigyakusan (四逆散) when they were in arm 2, and underwent a final efficacy evaluation at 8 weeks.

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 of cold, menstruation, use of hormones, tongue diagnosis, abdominal examination, etc. In patients with each *sho* (証, pattern), efficacy for breast pain and mammary gland swelling, and symptoms of mastopathy was judged from patient complaints.

7. Main results

There were 68 dropouts. Shigyakusan and keishibukuryogan had similar efficacy.

8. Conclusions

No definite conclusions were reached.

9. From Kampo medicine perspective

Mastopathy is frequently treated with *kuoketsuzai* (驅才血劑, blood stasis-expelling formula); however, since its symptoms overlap with those of *kanqiukketsu* (肝氣鬱結, liver *qi* depression) including breast pain, shigyakusan, a saiko-agent, is important.

10. Safety assessment in the article

There were no adverse events.

11. Abstractor's comments

This study investigated the efficacy of shigyakusan, a different series of Kampo medicines from those of *oketsu* (才血) (blood stasis) treatment including keishibukuryogan, tokakujokito, and tokishakuyakusan. In this trial, keishibukuryogan was used as the control; however, since its efficacy has not been established, the results are quite obscure. If the efficacy of shigyakusan is to be considered a new therapeutic option, as intended by the author, more in-depth discussion of the indications for shigyakusan and keishibukuryogan will be needed. A follow-up report is awaited.

12. Abstractor and date

Nakata H, 10 January 2009, 1 June 2010.