

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

Samukawa K, Ogita S. Climacteric disorders and medicinal ginseng*. *Chiryogaku (Biomedicine & Therapeutics)* 1994; 28: 57–62 (in Japanese).

1. Objectives

To evaluate the clinical effect of kojimatsu (紅参末), tokishakuyakusan (当帰薬芍散), and their combination on climacteric disorders.

2. Design

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

3. Setting

One facility (the Department of Obstetrics and Gynecology, Osaka City University Hospital), Japan.

4. Participants

One-hundred and thirteen patients diagnosed with climacteric disorders and 124 postmenopausal women with unidentified complaints but not yet seen by a physician.

5. Intervention

Study 1: therapeutic effects on climacteric disorders

Arm 1: CHEONG-KWAN-JANG Kojimatsu (正官庄紅参末) 6 g/day (divided doses and time of administration not indicated) for 4 weeks (n=83).

Arm 2: KOTARO Tokishakuyakusan (当帰薬芍散) ryo Extract Granules 9 g/day (divided doses and time of administration not indicated) for 4 weeks (n=30).

Arm 3: CHEONG-KWAN-JANG Kojimatsu (正官庄紅参末) 6 g/day + KOTARO Tokishakuyakusan (当帰薬芍散) Extract Granules 9 g/day (divided doses and time of administration not indicated) (n=61).

Study 2: preventive effects on those who are likely to visit a hospital for climacteric disorders in future.

Arm 1: CHEONG-KWAN-JANG Kojimatsu (正官庄紅参末) 3 g/day (divided doses and time of administration not indicated) (n=36).

Arm 2: CHEONG-KWAN-JANG Kojimatsu (正官庄紅参末) 6 g/day (divided doses and time of administration not indicated) (n=20).

Arm 3: KOTARO Tokishakuyakusan (当帰薬芍散) ryo Extract Granules 9 g/day (divided doses and time of administration not indicated) (n=34).

Arm 4: CHEONG-KWAN-JANG Kojimatsu (正官庄紅参末) 3 g/day + KOTARO Tokishakuyakusan (当帰薬芍散) ryo Extract Granules 9 g/day (divided doses and time of administration not indicated) (n=34).

6. Main outcome measures

Improvement in clinical symptoms (decrease in Kupperman's index): marked improvement (80% or more decrease); moderate improvement (60–80% decrease); slight improvement (30–60% decrease); and no improvement (30% or less decrease). The evaluation in study 1 and study 2 was at 4 weeks and 8 weeks of treatment, respectively.

7. Main results

Study 1: Marked improvement occurred in a higher percentage of patients receiving kojimatsu alone (18.1%) or kojimatsu + tokishakuyakusan (19.7%) than in those receiving tokishakuyakusan alone (10.0%) ($P<0.05$). Moderate improvement occurred in a higher percentage of patients receiving the combination (47.5%) than in those receiving either tokishakuyakusan or kojimatsu alone (33.3% and 28.9%, respectively) ($P<0.01$).

Study 2: Kojimatsu alone tended to have a higher efficacy rate at 3 g/day than 6 g/day. Marked improvement occurred in considerably more subjects receiving the combination (32.4%) than in those receiving kojimatsu 6 g/day alone (5.0%), although there was no significant difference due to the small sample size.

8. Conclusions

Kojimatsu may improve the symptoms of climacteric disorders, and even more so when combined with tokishakuyakusan.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Not mentioned.

11. Abstractor's comments

This study concludes that the effect of kojimatsu on climacteric disorders in postmenopausal women is both therapeutic and preventive, widening the clinical application of Kampo formulations. However, it does not mention whether subjects with unidentified complaints had *qikyo* (気虚, *qi* deficiency), which needs kojimatsu, and how much they had *oketsu* (才血, blood stasis), *kekkyo* (血虚, blood deficiency), or *suidoku* (水毒, water toxin), which needs tokishakuyakusan combination. In-depth studies taking into account Kampo concepts of pathogenesis are desired in future.

12. Abstractor and date

Ushiyama T, 27 August 2008, 1 June 2010, 31 December 2013.