

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

Higuchi T, Tarakida A, Abe K, et al. Comparing the effects of hormone replacement therapy and kamishoyosan treatment on climacteric disorders\*. *Sanfujinka Kampo Kenkyu no Ayumi (Recent Progress of Kampo Medicine in Obstetrics and Gynecology)* 2009; 26: 18-23. Ichushi Web ID: 2009197632

**Higuchi T, Iino K, Tarakida A, et al. A comparing the effects of kamishoyosan or HRT on climacteric disorders in postmenopausal women: results from a randomized controlled trial. *Nihon Josei Igaku Gakkai Zasshi (The Journal of Japan Society for Menopause and Women's Health)* 2012; 20: 305-12 (in Japanese).**

**1. Objectives**

To evaluate effects of hormone replacement therapy (HRT) alone and in combination with kamishoyosan (加味逍遙散) on climacteric disorders.

**2. Design**

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

**3. Setting**

Study Group for Treatment of Menopausal Unidentified Complaints, Hirosaki University Hospital and twenty other centers, Japan.

**4. Participants**

One hundred and three patients who were diagnosed with climacteric disorders at the above-mentioned institutions and sought treatment.

**5. Intervention**

Arm 1: KSS group: TSUMURA Kamishoyosan (加味逍遙散) Extract Granules 2.5 g t.i.d. orally before meals for 8 weeks (n=35).

Arm 2: HRT group: conjugated estrogen formulations or 17β-estradiol patch for 8 weeks (in patients with uterine preservation, medroxyprogesterone acetate was concomitantly administered) (n=34).

Arm 3: Arm 1 + Arm 2 (KSS/HRT group; n=34)

**6. Main outcome measures**

Changes in climacteric symptom rating scale developed by the Japan Society of Obstetrics and Gynecology (JSOG), at 4 and 8 weeks of treatment from baseline.

**7. Main results**

Since six participants dropped out of arm 1, 10 from arm 2, and five from arm 3, the efficacy analysis set consisted of a total of 82 patients. 'Dizziness' improved significantly ( $P<0.05$ ) at Week 4 in arm 1 compared to arm 2. The rate of improvement for 'burning sensation in the head and upper body' was significantly higher ( $P<0.05$ ) in arm 2 than in arm 1 and the rate for 'proneness to sweating' was significantly higher ( $P<0.01$ ) in the HRT group than the KSS and the KSS/HRT groups. The KSS/HRT group demonstrated a significantly higher rate of improvement ( $P<0.05$ ) than the KSS and HRT groups for nocturnal waking and tightness in the chest.

**8. Conclusions**

As therapies for climacteric disorder, HRT and kamishoyosan demonstrate differing effects for different symptoms. Given the choices for their application and combined use, it would seem that asking patients about the details of their symptoms and carefully analyzing them would be beneficial.

**9. From Kampo medicine perspective**

None.

**10. Safety assessment in the article**

Not mentioned.

**11. Abstractor's comments**

This study compared the effects of kamishoyosan, the widely used conventional treatment for female climacteric disorder, and HRT, the standard therapy in Western medicine, and made certain evaluations. As speculated, the study reconfirmed that the effects of these therapies differ for different symptoms. That is, HRT demonstrates greater efficacy for vasomotor nerve disturbance symptoms, as diagnosed by Western medicine. Meanwhile, Kampo medical theory can explain the effects of kamishoyosan for hot flashes, palpitations, burning sensation, sweating in the upper body, and other symptoms. If possible, the authors should make their conclusions after using this study's protocols for comparison of kamishoyosan-pattern and non-kamishoyosan-pattern (非証) participants through rigorous pattern identification. My hope is that guidelines are formulated for appropriate usage with HRT according to Oriental medical principles and on the basis of diagnosis of the absence or presence of saiko-pattern or blood stasis, which would be relatively straightforward for a clinical physician. In terms of future practice, I also hope that the researchers take on the challenge of building the evidence base for proposing the incorporation of kamishoyosan into standard therapy in Japan for climacteric disorder.

**12. Abstractor and date**

Ushiroyama T, 1 June 2010, 31 December 2013.