

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

Yasui T, Matsui S, Yamamoto S, et al. Effects of Japanese traditional medicines on circulating cytokine levels in women with hot flashes. *Menopause* 2011; 18: 85–92. CENTRAL ID: CN-00787935, Pubmed ID: 20647958

1. Objectives

To evaluate the effects of keishibukuryogan (桂枝茯苓丸) and kamishoyosan (加味逍遙散) on levels of circulating cytokines in patients with hot flashes.

2. Design

Quasi-randomized controlled trial (Quasi-RCT).

3. Setting

Outpatients Clinic, Department of Obstetrics and Gynecology, Tokushima University Hospital, Japan.

4. Participants

One hundred twenty women with vasomotor symptoms (hot flashes, night sweats, etc.) but no use of drugs affecting the immune system within the previous year, including 17 women who received bilateral ovariectomy within the previous year and 103 perimenopausal women who were menstruating regularly (n=7), menstruating irregularly within the previous 12 months (n=51), and no longer menstruating (last menses within the previous year; n=45).

5. Intervention

Participants who wanted to receive treatment were allocated to arm 2 (odd-number days) or arm 3 (even-number days). Participants who did not want treatment were allocated to arm 1.

Arm 1: follow up only, no treatment (n=40).

Arm 2: TSUMURA Keishibukuryogan Extract Granules (2.5 g t.i.d) for 6 months (n=40).

Arm 3: TSUMURA Kamishoyosan Extract Granules (2.5 g t.i.d) for 6 months (n=40).

6. Main outcome measures

Hot flash symptoms (severe, moderate, or mild according to FDA hot flash assessment criteria); circulating levels of IL-1 β , IL-5, IL-6, IL-7, IL-8, IL-10, TNF- α , MCP-1, and MIP-1 β before and 6 months after administration.

7. Main results

Improvement rates in hot flashes were significantly higher in arm 2 and arm 3 compared to arm 1 ($P<0.01$). Comparisons before and after treatment in the hot flash improvement group showed that MCP-1, IL-8, and MIP-1 β decreased significantly in arm 2 ($P<0.05$ for both), while IL-6, IL-8, and MIP-1 β decreased significantly in arm 3 ($P<0.05$ for both).

8. Conclusions

Keishibukuryogan and Kamishoyosan improve hot flashes by lowering circulating levels of IL-8 and MCP-1, which are indicators of blood vessel inflammation.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Not mentioned.

11. Abstractor's comments

This article describes the therapeutic value and mechanism of action of keishibukuryogan and kamishoyosan in menopausal hot flashes. Animal research has shown that keishibukuryogan is effective for peripheral hot flashes mediated by calcitonin gene-related peptide, and kamishoyosan is effective for central hot flashes mediated by luteinizing hormone-releasing hormone; therefore, it may be possible to clarify the differences between keishibukuryogan and kamishoyosan by allocating participants according to their *sho* (証, pattern), using a medical questionnaire or the like. The outcomes of further research are anticipated.

12. Abstractor and date

Nakata H, 31 December 2012