

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

Plotnikoff GA, Watanabe K, Torkelson C, et al. The TU-025 Keishibukuryogan clinical trial for hot flash management in postmenopausal women: result and lessons for future research. *Menopause* 2011; 18: 8866-92. CENTRAL ID: CN-00810843, Pubmed ID: 21738077

1. Objectives

To evaluate the clinical effects of keishibukuryogan (桂枝茯苓丸) for hot flashes in menopausal American women.

2. Design

Randomized controlled trial (RCT).

3. Setting

Allina Center for Health Care Innovation (Minneapolis, MN, USA).

4. Participants

Participants were menopausal American women between 45 and 58 years with a hot flash score of at least 28 points/week (n=178).

5. Intervention

Arm 1: oral administration of TSUMURA Keishibukuryogan (桂枝茯苓丸) Extract Granules (12.5 g/day) for 12 weeks (n=57).

Arm 2: oral administration of TSUMURA Keishibukuryogan (桂枝茯苓丸) Extract Granules (7.5 g/day) for 12 weeks (n=62).

Arm 3: oral administration of placebo for 12 weeks (n=59).

6. Main outcome measures

The Greene Climacteric Index (GCI), Pittsburgh Sleep Quality Index (PSQI), and a hot flash scale score.

7. Main results

The hot flash scale score decreased significantly ($P<0.001$) in all groups 12 weeks after commencement of the study, however no significant difference was observed among the three groups. Similarly, no significant among-group difference was observed in the Greene Climacteric Index (GCI) or the Pittsburgh Sleep Quality Index (PSQI).

8. Conclusions

There is no difference between the effects of keishibukuryogan and placebo on overall climacteric disorder symptoms and sleep quality in American menopausal women.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

The incidence of diarrhea was 1.7% in the placebo group, but approximately 20% in the keishibukuryogan groups.

11. Abstractor's comments

This study tested the effects of keishibukuryogan on climacteric disorder, a traditional therapy used in Japan, with the researchers asking menopausal American women to score their symptoms, chiefly hot flashes. keishibukuryogan has been one of the main therapeutic Kampo medicines used for climacteric disorder; it is the subject of many academic articles, and its clinical effects have been reported from a variety of perspectives. The present study found that keishibukuryogan extract preparation, compared to placebo, did not improve outcome in American women. However, keishibukuryogan is not necessarily the first choice for symptoms such as hot flashes, which frequently occur in estrogen-deficiency and climacteric disorder. This study might have demonstrated the superiority of estrogen preparations, which are chiefly Western drugs. However, the study did compare keishibukuryogan's effects on menopausal women whose hot flash score exceeded a certain number and its results do not appear to negate the use of keishibukuryogan in therapy for menopausal women, who suffer a variety of unspecified complaints (especially *oketsu* [瘀血, blood stasis] conditions). The authors say they hang their hopes on the emergence of more effective trial methods to test the effectiveness of traditional therapies such as Kampo. One hopes that the development of such research will revolve around RCTs that compare groups according to objective data based on *sho* (証, pattern).

12. Abstractor and date

Ushiroyama T, 31 December 2012.