## **Evidence Reports of Kampo Treatment**

Task Force for Evidence Reports / Clinical Practice Guideline Committee for EBM, the Japan Society for Oriental Medicine

# 14. Genitourinary Tract Disorders (including Climacteric Disorders)

# Reference

Ushiroyama T, Ikeda A, Kakuma K, et al. Comparing the effects of estrogen and an herbal medicine on peripheral blood flow in post-menopausal women with hot flashes: hormone replacement therapy and gui-zhi-fu-ling-wan (keishibukuryogan), a Kampo medicine. *The American Journal of Chinese Medicine* 2005; 33: 259-67. CENTRAL ID: CN-00528621, Pubmed ID: 15974485

# 1. Objectives

To compare the efficacy of keishibukuryogan (桂枝茯苓丸) and hormone replacement therapy (HRT) for relief of hot flashes and chills.

## 2. Design

Randomized controlled trial (RCT).

# 3. Setting

None. (The authors belonged to the Department of Obstetrics and Gynecology, Osaka Medical College.), Japan

# 4. Participants

Three-hundred and fifty-two postmenopausal patients with hot flashes untreated with HRT in the past 3 months and without past history of chronic diseases, aged 46–58 years. Patients with coronary artery anomaly, thrombotic diseases, cerebral infarction, hypertension, renopathy, and allergic conditions were excluded.

# 5. Intervention

Arm 1: oral administration of 2.5 g of TSUMURA Keishibukuryogan (桂枝茯苓丸) (TJ-25) t.i.d. (daily dose 7.5 g).

Arm 2: oral administration of 0.625 mg of Premarin and 2.5 mg of Provera s.i.d. (i.e., HRT).

#### 6. Main outcome measures

Peripheral blood flow, measured pre- and post-administration by a laser Doppler velocimeter at 3 sites (jaw, finger tips, and toes).

# 7. Main results

Both HRT and keishibukuryogan reduced blood flow in the jaw and finger tips. Blood flow in the toes was increased by keishibukuryogan but unchanged by HRT.

## 8. Conclusions

Keishibukuryogan is effective for chills, especially in the legs, in patients with hot flashes. HRT is ineffective for chills. Although both HRT and keishibukuryogan are effective for hot flashes, the latter is more effective.

# 9. From Kampo medicine perspective

None.

# 10. Safety assessment in the article

Not mentioned.

## 11. Abstractor's comments

This study is a controlled trial of HRT and keishibukuryogan. It ensures objectivity by measuring hot flashes and chills in terms of blood flow. It would also be interesting to investigate how well these medicines change blood flow in patients without hot flashes.

# 12. Abstractor and date

Nakata H, 1 April 2008.