

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

Koike K, Ohno S, Takahashi N, et al. Efficacy of the herbal medicine unkei-to as an adjunctive treatment to hormone replacement therapy for postmenopausal women with depressive symptoms. *Clinical Neuropharmacology* 2004; 27: 157-62. CENTRAL ID: CN-00490860, Pubmed ID: 15319700

1. Objectives

To evaluate the efficacy of unkeito unkeito (温経湯) for climacteric disorders with depressive symptoms.

2. Design

Randomized cross-over controlled trial (RCT-cross over).

3. Setting

One university hospital and one clinic, Japan.

4. Participants

Twenty-four women with climacteric disorders with depressive symptoms and unresponsive to hormone replacement therapy (HRT).

5. Intervention

Arm 1: administration of 7.5 g/day of TSUMURA Unkeito (温経湯) Extract Granules for 6 months followed by administration of 7.5 g/day of TSUMURA Tokishakuyakusan (当帰芍薬散) Extract Granules for 6 months, with 1-month washout between interventions (n=12).

Arm 2: administration of 7.5 g/day of TSUMURA Tokishakuyakusan (当帰芍薬散) Extract Granules for 6 months followed by administration of 7.5 g/day of TSUMURA Unkeito (温経湯) Extract Granules for 6 months, with 1-month washout between interventions (n=12).

HRT was continued in both arms.

6. Main outcome measures

Zung's Self-Rating Depression Scale (ZSDS), State-Trait Anxiety Inventory (STAI-1, 2).

7. Main results

Administration of unkeito produced significant improvement in ZSDS and STAI-1, 2 at 3 months, which persisted to 6 months. The improvement in ZSDS and STAI-1, 2 was significantly greater after unkeito than tokishakuyakusan at both 3 months and 6 months.

8. Conclusions

Unkeito is effective as an adjuvant therapy for climacteric disorders with depressive symptoms in patients unresponsive to HRT, and has superior efficacy to that of tokishakuyakusan.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

No adverse drug reactions occurred.

11. Abstractor's comments

This study is a randomized cross-over trial of unkeito and tokishakuyakusan. It suggests that the mechanism of efficacy is the promotion of secretion of cytokine-induced neutrophil chemoattractant (CINC).

12. Abstractor and date

Kogure T, 15 June 2007, 1 April 2008, 31 December 2013.