

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

Takamatsu K, Fujii E, Mizuno H, et al. An investigation of the usefulness of nyoshinsan for climacteric disorder*. *Sanfujinka Kampo Kenkyu no Ayumi (Recent Progress of Kampo Medicine in Obstetrics and Gynecology)* 2003; 20: 95-100 (in Japanese).

1. Objectives

To verify the efficacy of nyoshinsan (女神散) for female climacteric disorder.

2. Design

Quasi-randomized controlled trial (quasi-RCT).

3. Setting

One center: Tokyo Women's Medical University Hospital, Japan.

4. Participants

Eighty-eight post-menopausal women referred to a menopausal outpatient clinic for climacteric disorder between November 2000 and January 2002.

5. Intervention

Arm 1: TJ-67 group: TSUMURA Nyoshinsan (女神散) Extract Granules (2.5 g t.i.d.) taken before meals (n=18).

Arm 2: TSUMURA Tokishakuyakusan (当帰芍薬散) Extract Granules (2.5 g t.i.d.) taken orally before meals (n=23).

Arm 3: TSUMURA Kamishoyosan (加味逍遙散) Extract Granules (2.5 g t.i.d.) taken orally before meals (n=23).

Arm 4: TSUMURA Keishibukuryogan (桂枝茯苓丸) Extract Granules (2.5 g t.i.d.) taken orally before meals (n=24).

The administration period was 4–8 weeks, depending on the patient.

6. Main outcome measures

Objective evaluation of symptom changes and their details.

(Keio menopausal index questionnaire, Self-rating Depression Scale [SDS] questionnaire).

7. Main results

There was no significant difference in the overall results for climacteric disorder between arm 1 and arms 2 to 4 collectively, and between each arm. The effect on the psychiatric symptoms of nocturnal awakening and depression appeared to be strong in arm 1. The effect on symptoms least affected by treatment was about the same in arm 1 and in arms 2 to 4. 'Palpitations', the symptom most responsive to treatment in arms 2 to 4, was significantly less responsive to treatment in arm 1, while comparison with each formulation showed a significant difference to arm 2 and to arm 3. The raw SDS scores changed significantly in response to treatment in arms 2 to 4 collectively and also to arm 4 individually ($P<0.05$), but not in response to treatment in arm 1. Among the patients in arm 1 with a BMI of 18.5–23, nyoshinsan had a significantly greater effect on those with higher BMI ($P<0.01$).

8. Conclusions

Nyoshinsan and the three major conventional Kampo medications for women (tokishakuyakusan, kamishoyosan, and keishibukuryogan) have similar effects on female climacteric disorder. Therefore proactive inclusion of nyoshinsan into treatment options is recommended.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

There were no potentially problematic adverse effects.

11. Abstractor's comments

This study investigated and compared the effects of nyoshinsan for treatment of female climacteric disorder with those of tokishakuyakusan, kamishoyosan, and keishibukuryogan, which are considered the three major conventional Kampo medications for women. Although it was a randomized controlled trial that did not take pattern identification into account, it is worth noting that 66.7% of the effects of nyoshinsan, tokishakuyakusan, kamishoyosan, and keishibukuryogan were confirmed. The finding of greater effectiveness in women with relatively high BMI suggests that effectiveness could be increased by prescribing these medications on the basis of Kampo diagnosis of deficiency/excess pattern. However, to compare the results for nyoshinsan with the results for the three major conventional Kampo medications for women, by using the results from this four-group comparative study, undeniably presents the problem of multiplicity: essentially, the study requires randomization between two groups, nyoshinsan and the three major conventional Kampo medications for women. Further study offers some promise.

12. Abstractor and date

Ushiroyama T, 31 December 2013.