

**2. Cancer (Condition after Cancer Surgery and Unspecified Adverse Drug Reactions of Anti-cancer Drugs)****14. Genitourinary Tract Disorders (including Climacteric Disorders)****Reference**

Yoshimura A, Sawada K, Sasano T, et al. Effect of Japanese Kampo medicine therapy for menopausal symptoms after treatment of gynecological malignancy. *Obstetrics and Gynecology International* 2018; 1-6. Pubmed ID: 29805451

**1. Objectives**

To evaluate the effect of Kampo medicines kamikihito (加味帰脾湯) and kamishoyosan (加味逍遙散) on menopausal symptoms in gynecological cancer patients.

**2. Design**

Randomized controlled trial using envelopes for allocation (RCT-envelope).

**3. Setting**

One university hospital (Osaka University Hospital), Japan.

**4. Participants**

Patients who had menopausal symptoms after receiving treatment of gynecological malignancy between November 2012 and December 2015, and had a Kupperman Menopausal Index (KI) total score of 21 (Moderate) or more. Exclusion criteria were receiving Kampo preparations, herbal preparations, or hormone replacement therapy; a history of or being suspected of having aldosteronism; myopathy, or hypokalemia.

**5. Intervention**

Arm 1: KRACIE Kamikihito (加味帰脾湯) Extract Fine Granules 3.75 g b.i.d. (before or with a meal) for 8 weeks (n=18).

Arm 2: KRACIE Kamishoyosan (加味逍遙散) Extract Fine Granules 3.0 g b.i.d. (before or with a meal) for 8 weeks (n=15).

**6. Main outcome measures**

The treatment was given for 8 weeks. A KI questionnaire was used to assess subjective symptoms, and the KI total score and each domain score were examined. For the safety evaluation, any adverse events during the study period were evaluated.

**7. Main results**

Three patients in Arm 1 and 1 patient in Arm 2 were withdrawn from the study, and missing data were noted in 1 patient in Arm 1. Thus, the analysis of therapeutic efficacy was performed on 14 patients in Arm 1 and 14 patients in Arm 2. In both groups, the KI total scores before Kampo therapy (baseline) were significantly increased from the scores before anticancer therapy. After the start of Kampo therapy, the KI total scores decreased in both groups, and significantly improved from baseline at Weeks 4 and 8. Among the KI subscores, significant improvements were shown for 3 domains in Arm 1 and 6 domains in Arm 2.

**8. Conclusions**

Kampo therapy may contribute to the tailored medical management of patients with symptoms after receiving treatment for gynecologic malignancy, thus improving the patient's QOL.

**9. From Kampo medicine perspective**

None.

**10. Safety assessment in the article**

Two patients in Arm 1 had adverse events of unknown causality (i.e., diarrhea in 1 patient and joint pain in another patient).

**11. Abstractor's comments**

This clinical study is of interest in that it was designed to determine the effect of Kampo medicines on menopausal symptoms after treatment of cancer. Some menopausal symptoms after treatment of cancer are speculated to improve with the administration of Kampo medicines. This study compared two Kampo medicines of kamikihito and kamishoyosan, and showed that both were effective, with no significant difference between the two groups. As an RCT, however, adequate selection of the control group should be an issue. Further studies in more patients and the determination of similar effects of other Kampo medicines are awaited.

**12. Abstractor and date**

Kato Y, 1 September 2019.