

2. Cancer (Condition after Cancer Surgery and Unspecified Adverse Drug Reactions of Anti-cancer Drugs)**Reference**

Miyabe Y, Taniguchi C, Kawashima M, et al. Effect of Kampo medicines (sokeikakketsuto, shakuyakukanzoto) for taxol-caused peripheral nerve disorder – evaluation by current perception threshold measured by Neurometer®. *Sanfujinka Kampo Kenkyu no Ayumi (Recent Progress of Kampo Medicine in Obstetrics and Gynecology)* 2006; 23: 65-8 (in Japanese).

1. Objectives

To evaluate the potential use of sokeikakketsuto (疎経活血湯) and shakuyakukanzoto (芍薬甘草湯) in preventing peripheral nerve disorder in patients receiving taxol.

2. Design

A randomized crossover controlled trial (RCT-crossover).

3. Setting

Department of Obstetrics and Gynecology, Hamamatsu University School of Medicine, University Hospital, Japan.

4. Participants

Seven patients who received monthly paclitaxel–carboplatin (TJ) as the initial anticancer therapy (18 cycles) for gynecological malignant tumors (ovarian cancer, uterine cervical cancer, and endometrial cancer) at the above facility between April 2002 and March 2005.

5. Intervention

Since allocation to these treatment arms is not described, the treatment arms are described in terms of treatment regimen.

Arm 1: monthly TJ + oral administration of Kampo medicines (sokeikakketsuto (疎経活血湯), shakuyakukanzoto (芍薬甘草湯)) (manufacturer unknown) before meals for 14 days before and after TJ therapy.

Arm 2: monthly TJ.

6. Main outcome measures

Current perception threshold (CPT) measured by Neurometer® (2000 Hz, 250 Hz, and 5 Hz) 7 days before and 7 days after the start of TJ therapy: CPT value.

7. Main results

The value (predose CPT – postdose CPT)/predose CPT × 100 (%) decreased after TJ therapy, indicating deteriorating perception without Kampo treatment but remained unchanged with Kampo treatment.

8. Conclusions

TJ therapy when combined with Kampo medicines (sokeikakketsuto, shakuyakukanzoto), but not TJ therapy alone, reduces the severity of peripheral nerve disorder.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Administration of medicines caused no adverse drug reactions.

11. Abstractor's comments

This is a valuable study verifying the efficacy of sokeikakketsuto and shakuyakukanzoto for peripheral nerve disorder, an occasional adverse reaction to anticancer drug treatment that is evaluated by current perception threshold measurement. However, considering the small sample size (7 subjects), individual characteristics may greatly affect and bias the results; thus, increased number of cases may change the results. It is also important to ensure symptoms are consistent and relief of actual symptoms is documented by measured values, warranting continued research efforts. Furthermore, logically, the effect of a Kampo medicine is not constant but depends on the physical status of the host in each cycle of anticancer therapy. Therefore, identification of the “*sho*” (証, pattern) of each individual in each cycle is recommended to investigate the correlation between pathological analysis in Kampo medicine and the objective evaluation by current perception threshold used in this study. This may lead to proper usage of Kampo medicines and establishment of highly effective regimens in cancer treatment.

12. Abstractor and date

Ushiroyama T, 19 December 2008, 1 June 2010, 31 December 2013.