

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

Hasegawa K, Mizutani Y, Kuramoto H, et al. The Effect of L-glutamine and shakuyaku-kanzo-to for paclitaxel-induced myalgia/arthralgia. *Gan to Kagaku Ryoho (Japanese Journal of Cancer and Chemotherapy)* 2002; 29: 569-74 (in Japanese with English abstract). Ichushi Web ID: 2002217069 [MOL](#), [MOL-Lib](#)

**1. Objectives**

To evaluate the efficacy and safety of shakuyakukanzoto (芍薬甘草湯) and L-glutamine for paclitaxel-induced myalgia and arthralgia.

**2. Design**

Crossover randomized controlled trial (RCT-crossover).

**3. Setting**

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**4. Participants**

Fifteen patients with ovarian (n=13), cervical (n=1), or vulva (n=1) cancer who: 1) had received chemotherapy including paclitaxel (TXL) in December 1999 through July 2000; 2) had developed myalgia and arthralgia; and 3) were scheduled for 2 or more cycles of chemotherapy. The data from twelve of these patients were analyzed.

**5. Intervention**

Arm 1: TXL treatment combined with shakuyakukanzoto (芍薬甘草湯) 7.5 g/day (three divided doses) in the second cycle and with L-glutamine 2.0 g/day (three divided doses) in the third cycle, in 7 patients.

Arm 2: TXL treatment combined with L-glutamine 2.0 g/day (three divided doses) in the second cycle and with shakuyakukanzoto (芍薬甘草湯) 7.5 g/day (three divided doses) in the third cycle, in 8 patients.

The first cycle (TXL monotherapy), in which pain occurred, was considered to be a control.

Shakuyakukanzoto (芍薬甘草湯) and L-glutamine were orally administered from 1 week before the TXL treatment until the pain resolved.

A single dose of an NSAID (Voltaren: 25 mg) was given if the effects of test drugs were poor. The washout period was at least one week

**6. Main outcome measures**

The efficacy was evaluated based on: 1) sum of pain scores; 2) duration of myalgia and arthralgia; 3) duration of grade 2 or greater myalgia and arthralgia; 4) number of analgesics used; and 5) final subjective impressions.

**7. Main results**

Twelve patients were evaluated in the final analysis. Reductions of the duration of myalgia and arthralgia were significantly different between the control and the L-glutamine-treated patients. Reductions of the duration of grade 2 or greater myalgia and arthralgia in the shakuyakukanzoto- and the L-glutamine-treated patients differed significantly from that of the control patients. No significant differences occurred in any variable between the shakuyakukanzoto- and the L-glutamine-treated patients.

**8. Conclusions**

Shakuyakukanzoto and L-glutamine have no dramatic effects on paclitaxel-induced myalgia and arthralgia, except for the reduction of the duration of grade 2 or greater pain.

**9. From Kampo medicine perspective**

None.

**10. Safety assessment in the article**

One L-glutamine-treated patient reported nausea and one shakuyakukanzoto-treated patient could not take the drug for an unspecified reason.

**11. Abstractor's comments**

Shakuyakukanzoto is effective for pains associated with smooth and skeletal muscle spasm. In contrast, arthralgia (a paclitaxel-induced adverse reaction) is not included as an indication for treatment with shakuyakukanzoto. However, excellent responses were reported in the present study. The efficacy of this drug for this indication might be confirmed in the future by increasing the number of patients, as well as by identifying candidate patients for this treatment from an analysis of responders and non-responders.

**12. Abstractor and date**

Okabe T, 15 June 2007, 1 April 2008, 1 June 2010, 31 December 2013.