

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

Yoshida T, Sawa T, Ishiguro T, et al. The efficacy of prophylactic Shakuyaku-Kanzo-to for myalgia and arthralgia following carboplatin and paclitaxel combination chemotherapy for non-small cell lung cancer. *Support Care Cancer* 2009; 17: 315-20.

1. Objectives

To evaluate the preventive effect of shakuyakukanzoto (芍薬甘草湯) for arthralgia and myalgia following carboplatin and paclitaxel combination chemotherapy for non-small cell lung cancer

2. Design

Randomized controlled trial (RCT).

3. Setting

1 hospital, Japan.

4. Participants

50 unresectable, advanced, non-small cell lung cancer patients.

5. Intervention

Arm 1: TSUMURA Shakuyakukanzoto (芍薬甘草湯) Extract Granules 7.5g/day (2.5g t.i.d. before meals) taken orally from the day of chemotherapy (day 1) to day 21 (n=25).

Arm 2: No administration (n=25).

6. Main outcome measures

Primary endpoints: Myalgia and arthralgia grade (JCOG-CTC).

Secondary endpoints: Myalgia and arthralgia duration, number of patients requiring additional non-steroidal anti-inflammatory drugs (NSAIDs) administration.

7. Main results

Primary endpoints: Myalgia and arthralgia grades were significantly lower in the shakuyakukanzoto group ($P=0.018$). Secondary endpoints: Pain durations were significantly shorter ($P=0.002$), and the numbers of patients requiring additional NSAID administration were significantly lower ($P=0.036$) in the shakuyakukanzoto group.

8. Conclusion

Shakuyakukanzoto alleviates arthralgia and myalgia following carboplatin and paclitaxel combination chemotherapy.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Duodenal ulcer, possibly attributable to NSAIDs, occurred in one participant in the control group.

11. Abstractor's comments

Paclitaxel sometimes causes arthralgia and myalgia. The promotion of prostaglandin production is thought to be one of the causative factors, and NSAIDs are commonly used for it. However, NSAIDs have adverse effects, such as peptic ulcer. There is great significance in this study having verified the effectiveness of preventive administration of shakuyakukanzoto through an RCT. The authors also mention that continued administration of shakuyakukanzoto from cycle 2 resulted in a significantly higher number of chemotherapy cycles ($P=0.001$) and that the anti-tumor effects (response rate) tended to be higher in the administration group compared to the control group ($P=0.113$). This outcome is real corroboration of the concept of using Kampo to allow for the successful completion of standard therapies. Although 7.5g of shakuyakukanzoto was continually administered daily, there was no case of pseudoaldosteronism. The authors raise some problematic points such as the high number of patients with good PS in the shakuyakukanzoto group, the differences in initial paclitaxel doses, the lack of a placebo in the control group, and the small number of participants. Hopefully they will conduct another RCT that resolves those problems.

12. Abstractor and date

Motoo Y, 25 January 2017.